



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: United States Patent No. 7,351,533

Granted: April 1, 2008

To: Michael P. McCarthy and JoAnne A. Suzich

FOR: IN VITRO METHOD FOR DISASSEMBLY/REASSEMBLY OF  
PAPILLOMAVIRUS VIRUS-LIKE PARTICLES (VLPS), HOMOGENOUS  
VLP AND CAPSOMERE COMPOSITIONS PRODUCED BY SAID  
METHODS: USE THEREOF AS VEHICLE FOR IMPROVED  
PURIFICATION, AND DELIVERY OF ACTIVE AGENTS

Commissioner for Patents  
U.S. Patent and Trademark Office  
Commissioner for Patents  
**Mail Stop Hatch-Waxman PTE**  
Alexandria, VA 22313

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**APPLICATION FOR EXTENSION OF PATENT TERM**

**UNDER 35 U.S.C. § 156**

Sir:

MedImmune, LLC. hereby requests an extension of the patent term of United States Patent No. 7,351,533 (hereinafter referred to as "U.S. Patent No. 7,351,533") under 35 U.S.C. § 156.

Applicant, MedImmune, LLC., a corporation created and existing under the laws of the State of Delaware, represents that it is the owner of record of U.S. Patent No. 7,351,533 by virtue of an assignment from the inventors thereof recorded on March 15, 2004 at Reel 015094, Frame 0574. A copy of the assignment is included herewith as **Exhibit 1**.

The following information is submitted in accordance with 35 U.S.C. § 156(d) and 37

C.F.R. § 1.710 *et seq.*, and follows the numerical sequence and format as set forth in 37 C.F.R.

§ 1.740(a):

- (1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics.**

The approved product is CERVARIX. The approved product is supplied as a sterile suspension for intramuscular injection. A copy of the label identifying the approved product is included herewith as **Exhibit 2**. CERVARIX [Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant] is a non-infectious recombinant, AS04-adjuvanted vaccine that contains recombinant L1 protein, the major antigenic protein of the capsid, of oncogenic HPV types 16 and 18. The L1 proteins are produced in separate bioreactors using the recombinant Baculovirus expression vector system in a serum-free culture media composed of chemically-defined lipids, vitamins, amino acids, and mineral salts. Following replication of the L1 encoding recombinant Baculovirus in *Trichoplusia ni* insect cells, the L1 protein accumulates in the cytoplasm of the cells. The L1 proteins are released by cell disruption and purified by a series of chromatographic and filtration methods. Assembly of the L1 proteins into virus-like particles (VLPs) occurs at the end of the purification process.

- (2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred.**

The approved product was subject to regulatory review under Section 351 of the Public Health Service Act (codified at 42 U.S.C. § 262).

- (3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred.**

The approved product received permission for commercial marketing or use under Section 351 of the Public Health Service Act (42 U.S.C. § 262) on October 16, 2009. A copy of the approval letter is included herewith as **Exhibit 3**.

- (4) **In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.**

As active ingredients the approved product contains 20 mcg of HPV type 16 truncated L1 protein and 20 mcg of HPV type 18 truncated L1 protein. The truncated L1 proteins are produced in separate bioreactors in recombinant *Trichoplusia ni* cells and self-assembled into VLPs. The active ingredients of the approved product have not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum -Toxin Act.

- (5) **A statement that the application is being submitted within the sixty-day period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted.**

This application for extension of patent term under 35 U.S.C. § 156 is being submitted within the sixty-day period permitted for submission under 37 C.F.R. § 1.720(f). The last day on which this application could be submitted is December 15, 2009.

- (6) **A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration.**

The patent for which an extension is being sought is identified as follows:

Inventors:	Michael P. McCarthy JoAnne A. Suzich
U.S. Patent No.:	7,351,533
Issue Date:	April 1, 2008
Expiration Date:	September 5, 2017

- (7) **A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings.**

A copy of U.S. Patent No. 7,351,533 is included herewith as **Exhibit 4**.

- (8) **A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.**

No maintenance fees are currently due.

Copies of terminal disclaimers submitted during the prosecution of U.S. Patent No. 7,351,533 are included herewith as **Exhibit 5**.

- (9) **A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:**

- (i) **The approved product, if the listed claims include any claim to the approved product;**
- (ii) **The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and**
- (iii) **The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product.**

As described on page 12 of the Approved Label (**Exhibit 2**), the approved product is a non-infectious recombinant, AS04-adjuvanted vaccine that contains recombinant L1 protein, the major antigenic protein of the capsid, of oncogenic HPV types 16 and 18. The L1 proteins are produced in separate bioreactors using the recombinant Baculovirus expression vector system in a serum-free culture media composed of chemically-defined lipids, vitamins, amino acids, and mineral salts. Following replication of the L1 encoding recombinant Baculovirus in *Trichoplusia ni* insect cells, the L1 protein accumulates in the cytoplasm of the cells. The L1 proteins are released by cell disruption and purified by a series of chromatographic and filtration methods. Assembly of the L1 proteins into virus-like particles (VLPs) occurs at the end of the purification process. The purified, non-infectious VLPs are then adsorbed on to aluminum (as hydroxide salt). The adjuvant system, AS04, is composed of 3-O-desacyl-4'-monophosphoryl lipid A (MPL) adsorbed on to aluminum (as hydroxide salt).

The approved produce is prepared by combining the adsorbed VLPs of each HPV type



together with the AS04 adjuvant system in sodium chloride, sodium dihydrogen phosphate dehydrate, and Water for Injection.

U.S. Patent No. 7,351,533 claims the method of manufacturing the approved product. Specifically, Claims 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 14, and 15 read on methods of manufacturing the approved product as demonstrated below:

Claim:

1. A method of producing purified human papillomavirus (HPV) virus-like particles (VLPs) comprising: purifying a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains said recombinantly expressed HPV L1 protein or truncated version thereof in a form other than a VLP; and assembling said recombinantly expressed HPV L1 protein or truncated version thereof into purified human papillomavirus virus-like particles (VLPs).

2. The method of claim 1 wherein said human papillomavirus VLPs are selected from the group consisting of HPV-6, HPV-11, HPV-16, HPV-18, HPV-30, HPV-31, HPV-33, HPV-35, HPV-39, HPV-41, HPV-42, HPV-43, HPV-44, HPV-45, HPV-52, HPV-54, HPV-55, HPV-56, HPV-58, HPV-70, and mixtures thereof.

3. The method of claim 2 wherein said human papillomavirus VLP is an HPV-16 VLP.

4. The method of claim 2 wherein said human papillomavirus VLPs are HPV-16 VLPs and HPV-18 VLPs.

6. The method of claim 1 wherein said reducing agent is a sulfhydryl reducing agent.

7. The method of claim 6 wherein said sulfhydryl reducing agent is

β-mercaptoethanol.

8. The method of claim 1 wherein assembly of said HPV L1 protein or truncated version thereof is induced by oxidation or removal of said reducing agent.

9. A method of producing purified human papillomavirus (HPV) virus-like particles (VLPs), comprising: purifying a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains said recombinantly expressed HPV L1 protein or truncated version thereof in a form other than a VLP; and assembling said recombinantly expressed HPV L1 protein or truncated version thereof into purified human papillomavirus virus-like particles (VLPs) by removing or oxidizing said at least one reducing agent.

10. The method of claim 9 wherein said human papillomavirus VLPs are selected from the group consisting of HPV-6, HPV-11, HPV-16, HPV-18, HPV-30, HPV-31, HPV-33, HPV-35, HPV-39, HPV-41, HPV-42, HPV-43, HPV-44, HPV-45, HPV-52, HPV-54, HPV-55, HPV-56, HPV-58, HPV-70, and mixtures thereof.

11. The method of claim 10 wherein said human papillomavirus VLP is an HPV-16 VLP.

12. The method of claim 10 wherein said human papillomavirus VLPs are HPV-16 VLPs and HPV-18 VLPs.

14. The method of claim 9 wherein said reducing agent is a sulfhydryl reducing agent.

15. The method of claim 14 wherein said sulfhydryl reducing agent is 13-mercaptoethanol.

Manufacturing the approved product involves "purifying a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains said recombinantly expressed HPV L1 protein or truncated version thereof in a form other than a VLP; and assembling said recombinantly expressed HPV L1 protein or truncated version thereof into purified human papillomavirus virus-like particles (VLPs)." Manufacturing the approved product also involves "purifying a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains said recombinantly expressed HPV L1 protein or truncated version thereof in a form other than a VLP; and assembling said recombinantly expressed HPV L1 protein or truncated version thereof into purified human papillomavirus virus-like particles (VLPs) by removing or oxidizing said at least one reducing agent." The reducing agent used in the production of the approved product is the sulthydryl reducing agent,  $\beta$ -mercaptoethanol. Thus, claims 1, 6, 7, 8, 9, 14, and 15 of U.S. Patent No. 7,351,533 read on the methods of manufacturing the approved product.

The approved product includes L1 VLPs of HPV types 16 and 18. Thus, claims 2, 3, 4, 10, 11, and 12 of U.S. Patent No. 7,351,533 read on the methods of manufacturing the approved product.

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product:

A. The effective date of the investigational new drug (IND) application and the IND number;

B. The date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number; and

C. The date on which the NDA was approved or the Product License issued.

The effective date of the IND application for approved product was September 8, 1998. The IND application was assigned number FDA IND #BB-IND-7920. A copy of the letter from the FDA acknowledging receipt of the IND application is included herewith as **Exhibit 6**.

The effective date of the BLA application for the approved product was March 29, 2007. The BLA was assigned submission tracking number BL 125259/0. A copy of the letter from FDA acknowledging receipt of this BLA is included herewith as **Exhibit 7**.

The BLA was approved by the FDA approval letter dated and sent October 16, 2009, setting the effective date of the approval as the October 16, 2009 date of the letter. A copy of the approval letter is included herewith as **Exhibit 3**.

- (11) **A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.**

A brief description of the significant activities undertaken by the Applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities is included herewith as **Exhibit 8**. **Exhibit 8** consists of the following two parts:

**Exhibit 8A** is a chronology of submissions to and from FDA for IND #BB-IND-7920.

**Exhibit 8B** is a chronology of submissions to and from FDA for BLA BL 125259/0.

- (12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined.**

Statement that the Patent is Eligible for Extension:

In Applicant's opinion, U.S. Patent No. 7,351,533 is eligible for extension under 35 U.S.C. § 156 because it satisfies all of the requirements for such extension as follows:

35 U.S.C. § 156(a)

U.S. Patent No. 7,351,533 claims a method of manufacturing the approved product, as demonstrated in item (9) above.

35 U.S.C. § 156(a)(1)

The term of U.S. Patent No. 7,351,533 currently expires September 5, 2017. Thus, the term of U.S. Patent No. 7,351,533 has not expired before the submission of this application for extension.

35 U.S.C. § 156(a)(2)

The term of U.S. Patent No. 7,351,533 has never been extended.

35 U.S.C. § 156(a)(3)

The application for extension is submitted by the owner of record of U.S. Patent No. 7,351,533 in accordance with the requirements of 35 U.S.C. § 156(d) and the rules of the U.S. Patent and Trademark Office.

35 U.S.C. § 156(a)(4)

The approved product has been subject to a regulatory review period before its commercial marketing or use.

35 U.S.C. § 156(a)(5)(A)

The permission for the commercial marketing or use of the approved product after the regulatory

review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

Statement as to Length of Extension Claimed:

In accordance with 35 U.S.C. § 156(g) and the implementing regulations of 37 C.F.R. § 1.775, the length of the extension claimed was determined as follows:

37 C.F.R. § 1.775(b): Length of extension

The term of U.S. Patent No. 7,351,533 should be extended by 562 days [the regulatory review period under 37 C.F.R. § 1.775(c) less reductions under 37 C.F.R. § 1.775(d)] from September 5, 2017 to March 21, 2019.

37 C.F.R. § 1.775(c): Regulatory review period

The IND testing period defined in paragraph (c)(1) is 3490 days. This period extends from the effective date of IND #BB-IND-7920 on September 8, 1998 to the filing of BLA BL 125259/0 on March 29, 2008.

The BLA approval period defined in paragraph (c)(2) is 566 days. This period extends from the filing of BLA BL 125259/0 on March 29, 2008 to the date of approval of BLA BL 125259/0 on October 16, 2009.

Thus the regulatory review period under 37 C.F.R. § 1.775(c) [the sum of the periods of paragraphs (c)(1) and (c)(2)] is 4056 days.

37 C.F.R. § 1.775(d): Reductions

The reduction under paragraph (d)(1)(i) is 3494 days. U.S. Patent No. 7,351,533 issued on April 1, 2008. Under 37 C.F.R. § 1.775(d)(1)(i), the number of days in the periods of paragraphs (c)(1) and (c)(2) which were on and before the date on which the patent issued shall be subtracted from the total number of days in the periods of paragraphs (c)(1) and (c)(2).

Accordingly, the number of days in the periods of paragraphs (c)(1) and (c)(2) is reduced by 3494 days.

The reduction under paragraph (d)(1)(ii) is 0 days. With respect to paragraph (d)(1)(ii), 35 U.S.C. 156(d)(2)(B) provides that if a petition is submitted to the Secretary not later than 180 days after publication of the determination of the applicable regulatory review period, upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making this determination shall notify the Director of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing, and shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Director of any revision of the determination and shall publish any such revision in the Federal Register. There has been no such petition or determination by the Secretary, and thus the number of days under (d)(1)(ii) is 0 days.

The reduction under paragraph (d)(1)(iii) is 0 days. One-half of the number of days remaining in the period defined by paragraph (c)(1) after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) is one-half of 0 days, which is 0 days.



The total reduction under paragraph (d)(1) is 3494 days. Subtracting 3494 days from the regulatory review period of 4056 days yields an extension of 562 days.

The extended term under paragraph (d)(2) is to March 21, 2019. The original term of U.S. Patent No. 7,351,533 is to September 5, 2017. U.S. Patent No. is subject to terminal disclaimers over U.S. Patent Nos. 6,962,777, 6,416,945, and 6,261,765, each of which patents has an original term to September 5, 2017. Thus, the term of U.S. Patent No. 7,351,533 is not shortened by terminal disclaimer. Adding 562 days to the original term of the patent results in an extended term to March 21, 2019.

The date under paragraph (d)(3) is October 16, 2023. Adding 14 years to October 16, 2009, the date of the approval of BLA BL 125259/0, results in the date October 16, 2023.

The date under paragraph (d)(4) is March 21, 2019. The earlier of March 21, 2019 and October 16, 2023 is March 21, 2019.

The date under paragraph (d)(5) is March 21, 2019. Paragraph (d)(5) applies since the original patent was issued after September 24, 1984. Adding 5 years to the original expiration date of U.S. Patent No. 7,351,533 of September 5, 2017 results in the date September 5, 2022. The earlier of March 21, 2019 and September 5, 2022 is March 21, 2019.

Thus, as calculated above, the term of U.S. Patent No. 7,351,533 should be extended by 562 days, from September 5, 2017 to March 21, 2019.

**(13) A statement that applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (see § 1.765).**

Applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to any determination of entitlement to the extension sought.

- (14) **The prescribed fee for receiving and acting upon the application for extension (see § 1.20(j)).**

As indicated in the transmittal letter submitted with this application, the Patent and Trademark Office is authorized to charge the filing fee of \$1,120.00 and any additional fees which may be required by this or any other related paper, or to credit any overpayment to Deposit Account No. 03-0678.

- (15) **The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed.**

Please address all inquiries and correspondence relating to this application for patent term extension to:

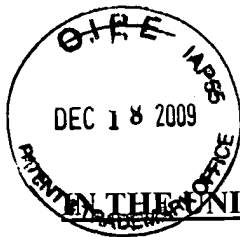
Raymond J. Lillie  
Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein  
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973-994-1700

Date: 12/14/09

Carella, Byrne, Bain, Gilfillan,  
Cecchi, Stewart & Olstein  
5 Becker Farm Road  
Roseland, NJ 07068

Respectfully Submitted,

By: Raymond J. Lillie  
Raymond J. Lillie  
Registration No. 31,778



**UNITED STATES PATENT AND TRADEMARK OFFICE**

**Patent Examining Operations**

Applicant(s): McCarthy, *et al.*

Serial No: 10/762,928

Art Unit: 1648

Filed: January 22, 2007

Examiner: Salimi

Title: In Vitro Method for Disassembly/Reassembly of Papillomavirus Virus-Like Particles (VLPs) Homogeneous VLP and Capsomere Compositions Produced by Said Methods; Use Thereof as Vehicle for Improved Purification, and Delivery of Active Agents

Docket No.: 469201.716

Customer No.: 27162

**TRANSMITTAL LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SIR:

Enclosed please find the following:

1. Application for Extension of Patent Term;
2. Exhibits 1 through 7, 8A and 8B;
3. Check in the amount of \$1,120.00; and
4. A self-addressed, postage paid, return receipt postcard, date stamp and return of which is respectfully requested.

The Commissioner is authorized to charge payment of any additional filing fees required under 37 C.F.R. 1.16 associated with this communication or credit any overpayment to Deposit Account No. 03-0678.



**FIRST CLASS CERTIFICATE**

I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

*Raymond J. Lillie*  
Raymond J. Lillie, Esq.

*12/14/09*  
Date

Respectfully submitted,

*Raymond J. Lillie*

Raymond J. Lillie, Esq.

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#385340 v1



# EXHIBIT 1

ASSIGNMENT

For good and valuable consideration, the receipt of which is hereby acknowledged, each of the undersigned, Michael P. McCarthy, and JoAnne A. Suzich, hereby sells, assigns and transfers to MedImmune, Inc. ("Assignee"), having a place of business at 35 West Watkins Mill Road, Gaithersburg, Maryland 20878, a corporation, its successors, assigns and legal representatives, his entire right, title and interest for the United States and all other countries, in and to the improvements(s) known as: United States Application Serial No. 10/762,928, filed 22 January 2004 and/or executed on even date herewith and is entitled:

**In Vitro Method for Disassembly/Reassembly of Papillomavirus Virus-Like Particles (VLPs), Homogeneous VLP and Capsomere Compositions Produced by Said Methods; Use Thereof as Vehicle for Improved Purification, and Delivery of Active Agents**

and in and to said application and all divisional, continuing, substitute, renewal, reissue and all other applications for Letters Patent which have been or shall be filed in the United States and all other countries on any of said improvements, and in and to all original, re-examined and reissued patents and extensions thereof which have been or shall be issued in the United States and all other countries on said improvements (hereinafter collectively, the "Improvements").

The undersigned further agrees that said Assignee may apply for and receive Letters Patent for said Improvements in its own name; and, when requested, without charge to but at the expense of Assignee, its successors, assigns and legal representatives, to carry out in good faith the intent and purpose of this assignment, the undersigned will execute all divisional, continuing, substitute, renewal, reissue and all other patent applications on all such Improvements; execute all rightful oaths, assignments, powers of attorney and other papers; communicate to said Assignee, its successors, assigns and representatives all facts known to the undersigned relating to said Improvements and the history thereof; and do everything possible which said Assignee, its successors, assigns or representatives shall consider desirable for aiding in securing and maintaining proper patent protection for said Improvements and for vesting title to said Improvements and all applications for patent and all patents on said Improvements in Assignee, its successors, assigns and representatives.

The undersigned hereby represents and warrants to Assignee, its successors, assigns and representatives that no assignment, grant, mortgage, license or other right or agreement affecting the rights and property herein conveyed has been made to others by the undersigned and that full right to convey the same as expressed herein is possessed by the undersigned.

The undersigned hereby grants power to John N. Bain (Reg. No. 18,651); John G. Gilfillan, III (Reg. No. 22,746); Elliot M. Olstein (Reg. No. 24,025); Raymond J. Lillie (Reg. No. 31,778); William Squire (Reg. No. 25,378); Alan J. Grant (Reg. No. 33,389); Francis C. Hand (Reg. No. 22,280); G. Glennon Troublefield (Reg. No. 39050); Raymond E. Stauffer (Reg. No. 47,109); and Michael A. Petrocelli (Reg. No. 53,461) to insert on this Assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document. Address correspondence and telephone calls to Raymond J. Lillie, c/o Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, 5 Becker Farm Road, Roseland, New Jersey 07068.

IN WITNESS WHEREOF, this Assignment is executed by the undersigned on the date(s) opposite their signature(s):

Inventor's Signature: \_\_\_\_\_

Michael P. McCarthy

Date: 03/09/04

STATE OF Maryland, COUNTY OF Montgomery : SS.:

Before me this 9th day of March, 2004, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

FELICIA D. ALEXANDER

NOTARY PUBLIC STATE OF MARYLAND

My Commission Expires November 1, 2005

Inventor's Signature: \_\_\_\_\_

JoAnne A. Suzich

Date: Mar 09, '04

STATE OF Maryland, COUNTY OF Montgomery : SS.:

Before me this 9th day of March, 2004, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

FELICIA D. ALEXANDER

NOTARY PUBLIC STATE OF MARYLAND

My Commission Expires November 1, 2005

CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN  
5 Becker Farm Road - Roseland, NJ 07068 - (973) 994-1700



## EXHIBIT 2

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use CERVARIX safely and effectively. See full prescribing information for CERVARIX.

**CERVARIX [Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant]**  
**Suspension for Intramuscular Injection**  
**Initial U.S. Approval: 2009**

### INDICATIONS AND USAGE

CERVARIX is a vaccine indicated for the prevention of the following diseases caused by oncogenic human papillomavirus (HPV) types 16 and 18:

- cervical cancer,
- cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma *in situ*, and
- cervical intraepithelial neoplasia (CIN) grade 1. (1.1)

CERVARIX is approved for use in females 10 through 25 years of age.

Limitations of Use and Effectiveness (1.2)

- CERVARIX does not provide protection against disease due to all HPV types. (14.3)
- CERVARIX has not been demonstrated to provide protection against disease from vaccine and non-vaccine HPV types to which a woman has previously been exposed through sexual activity. (14.2)

### DOSAGE AND ADMINISTRATION

Three doses (0.5-mL each) by intramuscular injection according to the following schedule: 0-, 1-, and 6-months. (2.2)

### DOSAGE FORMS AND STRENGTHS

0.5-mL suspension for injection as a single-dose vial or pre-filled syringe. (3)

### CONTRAINDICATIONS

Severe allergic reactions (e.g., anaphylaxis) to any component of CERVARIX. (4)

### WARNINGS AND PRECAUTIONS

- Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with CERVARIX. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position. (5.1)
- Do not use the prefilled syringes in latex sensitive individuals. (5.2)

### ADVERSE REACTIONS

- Most common local adverse reactions in  $\geq 20\%$  of subjects were pain, redness, and swelling at the injection site. (6.1)
- Most common general adverse events in  $\geq 20\%$  of subjects were fatigue, headache, myalgia, gastrointestinal symptoms, and arthralgia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

### DRUG INTERACTIONS

Do not mix CERVARIX with any other vaccine in the same syringe or vial. (7.1)

### USE IN SPECIFIC POPULATIONS

- Safety has not been established in pregnant women. Register women who receive CERVARIX while pregnant in the pregnancy registry by calling 1-888-452-9622. (8.1)
- Immunocompromised individuals may have a reduced immune response to CERVARIX. (8.6)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: Month Year  
CRX:XPI

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

#### **1.1 Indications**

CERVARIX® is indicated for the prevention of the following diseases caused by oncogenic human papillomavirus (HPV) types 16 and 18 [see *Clinical Studies (14)*]:

- cervical cancer,
- cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma *in situ*, and
- cervical intraepithelial neoplasia (CIN) grade 1.

CERVARIX is approved for use in females 10 through 25 years of age.

#### **1.2 Limitations of Use and Effectiveness**

CERVARIX does not provide protection against disease due to all HPV types [see *Clinical Studies (14.3)*].

CERVARIX has not been demonstrated to provide protection against disease from vaccine and non-vaccine HPV types to which a woman has previously been exposed through sexual activity [see *Clinical Studies (14.2)*].

Females should continue to adhere to recommended cervical cancer screening procedures [see *Patient Counseling Information (17)*].

Vaccination with CERVARIX may not result in protection in all vaccine recipients.

### **2 DOSAGE AND ADMINISTRATION**

#### **2.1 Preparation for Administration**

Shake vial or syringe well before withdrawal and use. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. CERVARIX also should be inspected visually for cracks in the vial or syringe prior to administration. If any of these conditions exist, the vaccine should not be administered. With thorough agitation, CERVARIX is a homogeneous, turbid, white suspension. Discard if it appears otherwise.

#### **2.2 Dose and Schedule**

Immunization with CERVARIX consists of 3 doses of 0.5-mL each, by intramuscular injection according to the following schedule: 0, 1, and 6 months. The preferred site of administration is the deltoid region of the upper arm.

Do not administer this product intravenously, intradermally, or subcutaneously.

### **3 DOSAGE FORMS AND STRENGTHS**

CERVARIX is a suspension for intramuscular injection available in 0.5-mL single-dose vials and prefilled TIP-LOK® syringes.

36 **4 CONTRAINDICATIONS**

37 Severe allergic reactions (e.g., anaphylaxis) to any component of CERVARIX [see  
38 *Description (11)*].

39 **5 WARNINGS AND PRECAUTIONS**

40 **5.1 Syncope**

41 Because vaccinees may develop syncope, sometimes resulting in falling with injury,  
42 observation for 15 minutes after administration is recommended. Syncope, sometimes associated  
43 with tonic-clonic movements and other seizure-like activity, has been reported following  
44 vaccination with CERVARIX. When syncope is associated with tonic-clonic movements, the  
45 activity is usually transient and typically responds to restoring cerebral perfusion by maintaining  
46 a supine or Trendelenburg position.

47 **5.2 Latex**

48 The tip cap and the rubber plunger of the needleless prefilled syringes contain dry natural  
49 latex rubber that may cause allergic reactions in latex sensitive individuals. The vial stopper does  
50 not contain latex.

51 **5.3 Preventing and Managing Allergic Vaccine Reactions**

52 Prior to administration, the healthcare provider should review the immunization history  
53 for possible vaccine hypersensitivity and previous vaccination-related adverse reactions to allow  
54 an assessment of benefits and risks. Appropriate medical treatment and supervision should be  
55 readily available in case of anaphylactic reactions following administration of CERVARIX.

56 **6 ADVERSE REACTIONS**

57 The most common local adverse reactions ( $\geq 20\%$  of subjects) were pain, redness, and  
58 swelling at the injection site.

59 The most common general adverse events ( $\geq 20\%$  of subjects) were fatigue, headache,  
60 myalgia, gastrointestinal symptoms, and arthralgia.

61 **6.1 Clinical Studies Experience**

62 Because clinical trials are conducted under widely varying conditions, adverse reaction  
63 rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the  
64 clinical trials of another vaccine, and may not reflect the rates observed in practice. There is the  
65 possibility that broad use of CERVARIX could reveal adverse reactions not observed in clinical  
66 trials.

67 Studies in Females 10 Through 25 Years of Age: The safety of CERVARIX was  
68 evaluated by pooling data from controlled and uncontrolled clinical trials involving 23,713  
69 females 10 through 25 years of age in the pre-licensure clinical development program. In these  
70 studies, 12,785 females (10 through 25 years of age) received at least one dose of CERVARIX  
71 and 10,928 females received at least one dose of a control [Hepatitis A Vaccine containing 360  
72 EL.U. (10 through 14 years of age), Hepatitis A Vaccine containing 720 EL.U. (15 through  
73 25 years of age), or Al(OH)<sub>3</sub> (500 mcg, 15 through 25 years of age)].

Data on solicited local and general adverse events were collected by subjects or parents using standardized diary cards for 7 consecutive days following each vaccine dose (i.e., day of vaccination and the next 6 days). Unsolicited adverse events were recorded with diary cards for 30-days following each vaccination (day of vaccination and 29 subsequent days). Parents and/or subjects were also asked at each study visit about the occurrence of any adverse events and instructed to immediately report serious adverse events throughout the study period. These studies were conducted in North America, Latin America, Europe, Asia, and Australia. Overall, the majority of subjects were white (59%), followed by Asian (26%), Hispanic (9%), black (3%), and other racial/ethnic groups (3%).

*Solicited Adverse Events:* The reported frequencies of solicited local injection site reactions (pain, redness, and swelling) and general adverse events (fatigue, fever, gastrointestinal symptoms, headache, arthralgia, myalgia, and urticaria) within 7 days after vaccination in females 10 through 25 years of age are presented in Table 1. An analysis of solicited local injection site reactions by dose is presented in Table 2. Local reactions were reported more frequently with CERVARIX when compared with the control groups; in  $\geq 84\%$  of recipients of CERVARIX, these local reactions were mild to moderate in intensity. Compared with dose 1, pain was reported less frequently after doses 2 and 3 of CERVARIX, in contrast to redness and swelling where there was a small increased incidence. There was no increase in the frequency of general adverse events with successive doses.

**Table 1. Rates of Solicited Local Adverse Reactions and General Adverse Events in Females 10 Through 25 Years of Age Within 7 Days of Vaccination (Total Vaccinated Cohort<sup>a</sup>)**

Adverse Reaction/Event	CERVARIX (10-25 yrs) %	HAV 720 <sup>b</sup> (15-25 yrs) %	HAV 360 <sup>c</sup> (10-14 yrs) %	Al(OH) <sub>3</sub> Control <sup>d</sup> (15-25 yrs) %
<b>Local Adverse Reaction</b>	<b>N = 6,431</b>	<b>N = 3,079</b>	<b>N = 1,027</b>	<b>N = 549</b>
Pain	91.8	78.0	64.2	87.2
Redness	48.0	27.6	25.2	24.4
Swelling	44.1	19.8	17.3	21.3
<b>General Adverse Event</b>	<b>N = 6,432</b>	<b>N = 3,079</b>	<b>N = 1,027</b>	<b>N = 549</b>
Fatigue	55.0	53.7	42.3	53.6
Headache	53.4	51.3	45.2	61.4
GI <sup>e</sup>	27.8	27.3	24.6	32.8
Fever (≥99.5°F)	12.8	10.9	16.0	13.5
Rash	9.6	8.4	6.7	10.0
	<b>N = 5,881</b>	<b>N = 3,079</b>	<b>N = 1,027</b>	—
Myalgia <sup>f</sup>	49.1	44.9	33.1	—
Arthralgia <sup>f</sup>	20.8	17.9	19.9	—
Urticaria <sup>f</sup>	7.4	7.9	5.4	—

<sup>a</sup> Total vaccinated cohort included subjects with at least one documented dose (N).

<sup>b</sup> HAV 720 = Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)<sub>3</sub>].

<sup>c</sup> HAV 360 = Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of Al(OH)<sub>3</sub>].

<sup>d</sup> Al(OH)<sub>3</sub> Control = control containing 500 mcg Al(OH)<sub>3</sub>.

<sup>e</sup> GI = Gastrointestinal symptoms, including nausea, vomiting, diarrhea, and/or abdominal pain.

<sup>f</sup> Adverse events solicited in a subset of subjects.

105 **Table 2. Rates of Solicited Local Adverse Reactions in Females 10 Through 25 Years of Age**  
 106 **by Dose Within 7 Days of Vaccination (Total Vaccinated Cohort<sup>a</sup>)**

Adverse Reaction	CERVARIX (10-25 yrs) %			HAV 720 <sup>b</sup> (15-25 yrs) %			HAV 360 <sup>c</sup> (10-14 yrs) %			Al(OH) <sub>3</sub> Control <sup>d</sup> (15-25 yrs) %		
	Post-Dose			Post-Dose			Post-Dose			Post-Dose		
	1	2	3	1	2	3	1	2	3	1	2	3
N	6,415	6,197	5,936	3,070	2,919	2,758	1,027	1,021	1,011	546	521	500
Pain	86.9	76.2	78.7	65.6	54.4	56.1	48.5	38.5	36.9	79.1	66.8	72.4
Pain, Grade 3 <sup>e</sup>	7.5	5.7	7.7	2.0	1.4	2.0	0.8	0.2	1.6	9.0	6.0	8.6
Redness	27.8	29.6	35.6	16.6	15.2	16.1	15.6	13.3	12.1	11.5	11.5	15.6
Redness, >50mm	0.2	0.5	1.0	0.1	0.1	0.0	0.1	0.2	0.1	0.2	0.0	0.0
Swelling	22.7	25.2	32.7	10.5	9.4	10.5	9.4	8.6	7.6	10.3	10.4	12.0
Swelling, >50mm	1.2	1.0	1.3	0.2	0.2	0.2	0.4	0.3	0.0	0.0	0.0	0.0

107 <sup>a</sup> Total vaccinated cohort included subjects with at least one documented dose (N).

108 <sup>b</sup> HAV 720 = Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)<sub>3</sub>].

109 <sup>c</sup> HAV 360 = Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of  
 110 Al(OH)<sub>3</sub>].

111 <sup>d</sup> Al(OH)<sub>3</sub> Control = control containing 500 mcg Al(OH)<sub>3</sub>.

112 <sup>e</sup> Defined as spontaneously painful or pain that prevented normal daily activities.

113

114 The pattern of solicited local adverse reactions and general adverse events following  
 115 administration of CERVARIX was similar between the age cohorts (10 through 14 years and 15  
 116 through 25 years).

117 *Unsolicited Adverse Events:* The frequency of unsolicited adverse events that  
 118 occurred within 30-days of vaccination (≥1% for CERVARIX and greater than any of the control  
 119 groups) in females 10 through 25 years of age are presented in Table 3.

120

121 **Table 3. Rates of Unsolicited Adverse Events in Females 10 Through 25 Years of Age**  
122 **Within 30 Days of Vaccination ( $\geq 1\%$  For CERVARIX and Greater Than HAV 720,**  
123 **HAV 360 or Al(OH)<sub>3</sub> Control) (Total Vaccinated Cohort<sup>a</sup>)**

Adverse Event	CERVARIX % (N = 6,654)	HAV 720 <sup>b</sup> % (N = 3,186)	HAV 360 <sup>c</sup> % (N = 1,032)	Al(OH) <sub>3</sub> Control <sup>d</sup> % (N = 581)
Headache	5.3	7.6	3.3	9.3
Nasopharyngitis	3.6	3.4	5.9	3.3
Influenza	3.2	5.6	1.3	1.9
Pharyngolaryngeal pain	2.9	2.7	2.2	2.2
Dizziness	2.2	2.6	1.5	3.1
Upper respiratory infection	2.0	1.3	6.7	1.5
Chlamydia infection	2.0	4.4	0.0	0.0
Dysmenorrhea	2.0	2.3	1.9	4.0
Pharyngitis	1.5	1.8	2.2	0.5
Injection site bruising	1.4	1.8	0.7	1.5
Vaginal infection	1.4	2.2	0.1	0.9
Injection site pruritus	1.3	0.5	0.6	0.2
Back pain	1.1	1.3	0.7	3.1
Urinary tract infection	1.0	1.4	0.3	1.2

124 <sup>a</sup> Total vaccinated cohort included subjects with at least one dose administered (N).

125 <sup>b</sup> HAV 720 = Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)<sub>3</sub>].

126 <sup>c</sup> HAV 360 = Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of  
127 Al(OH)<sub>3</sub>].

128 <sup>d</sup> Al(OH)<sub>3</sub> Control = control containing 500 mcg Al(OH)<sub>3</sub>.

129

130 ***New Onset Autoimmune Diseases (NOADs):*** The pooled safety database, which  
131 included controlled and uncontrolled trials which enrolled females 10 through 25 years of age,  
132 was searched for new medical conditions indicative of potential new onset autoimmune diseases.  
133 Overall, the incidence of potential NOADs, as well as NOADs, in the group receiving  
134 CERVARIX was 0.8% (95/12,533) and comparable to the pooled control group (0.8%,  
135 87/10,730) during the 4.3 years of follow-up (mean 3.0 years) (Table 4).

136 In the largest randomized, controlled trial (Study 2) which enrolled females 15 through  
137 25 years of age and which included active surveillance for potential NOADs, the incidence of  
138 potential NOADs and NOADs was 0.8% among subjects who received CERVARIX (78/9,319)  
139 and 0.8% among subjects who received Hepatitis A Vaccine [720 EL.U. of antigen and 500 mcg  
140 Al(OH)<sub>3</sub>] control (77/9,325).

141

142 **Table 4. Incidence of New Medical Conditions Indicative of Potential New Onset**  
143 **Autoimmune Disease and New Onset Autoimmune Disease Throughout the Follow-up**  
144 **Period Regardless of Causality in Females 10 Through 25 Years of Age (Total Vaccinated**  
145 **Cohort<sup>a</sup>)**

	<b>CERVARIX (N = 12,533)</b>	<b>Pooled Control Group<sup>b</sup> (N = 10,730)</b>
	<b>n (%)<sup>c</sup></b>	<b>n (%)<sup>c</sup></b>
<b>Total Number of Subjects With at Least One Medical Condition</b>	95 (0.8)	87 (0.8)
Arthritis <sup>d</sup>	9 (0.0)	4 (0.0)
Celiac disease	2 (0.0)	5 (0.0)
Dermatomyositis	0 (0.0)	1 (0.0)
Diabetes mellitus insulin-dependent (Type 1 or unspecified)	5 (0.0)	5 (0.0)
Erythema nodosum	3 (0.0)	0 (0.0)
Hyperthyroidism <sup>e</sup>	14 (0.1)	15 (0.1)
Hypothyroidism <sup>f</sup>	30 (0.2)	28 (0.3)
Inflammatory bowel disease <sup>g</sup>	8 (0.1)	4 (0.0)
Multiple sclerosis	4 (0.0)	1 (0.0)
Myelitis transverse	1 (0.0)	0 (0.0)
Optic neuritis/Optic neuritis retrobulbar	3 (0.0)	1 (0.0)
Psoriasis <sup>h</sup>	8 (0.1)	11 (0.1)
Raynaud's phenomenon	0 (0.0)	1 (0.0)
Rheumatoid arthritis	4 (0.0)	3 (0.0)
Systemic lupus erythematosus <sup>i</sup>	2 (0.0)	3 (0.0)
Thrombocytopenia <sup>j</sup>	1 (0.0)	1 (0.0)
Vasculitis <sup>k</sup>	1 (0.0)	3 (0.0)
Vitiligo	2 (0.0)	2 (0.0)

146 <sup>a</sup> Total vaccinated cohort included subjects with at least one documented dose (N).

147 <sup>b</sup> Pooled Control Group = Hepatitis A Vaccine control group [720 EL.U. of antigen and  
148 500 mcg Al(OH)<sub>3</sub>], Hepatitis A Vaccine control group [360 EL.U. of antigen and 250 mcg of  
149 Al(OH)<sub>3</sub>] and a control containing 500 mcg Al(OH)<sub>3</sub>.

150 <sup>c</sup> n (%): number and percentage of subjects with medical condition.

151 <sup>d</sup> Term includes reactive arthritis and arthritis.

152 <sup>e</sup> Term includes Basedow's disease, goiter, and hyperthyroidism.

153 <sup>f</sup> Term includes thyroiditis, autoimmune thyroiditis, and hypothyroidism.

154 <sup>g</sup> Term includes colitis ulcerative, Crohn's disease, proctitis ulcerative, and inflammatory bowel  
155 disease.

156 <sup>h</sup> Term includes psoriatic arthropathy, nail psoriasis, guttate psoriasis, and psoriasis.

157 <sup>i</sup> Term includes systemic lupus erythematosus and cutaneous lupus erythematosus.

158 <sup>j</sup> Term includes idiopathic thrombocytopenic purpura and thrombocytopenia.

159 <sup>k</sup> Term includes leukocytoclastic vasculitis and vasculitis.

160

161 **Serious Adverse Events:** In the pooled safety database, inclusive of controlled and  
162 uncontrolled studies, which enrolled females 10 through 72 years of age, 5.3% (862/16,142) of  
163 subjects who received CERVARIX and 5.9% (814/13,811) of subjects who received control  
164 reported at least one serious adverse event, without regard to causality, during the entire follow-  
165 up period (up to 7.4 years).

166 Among females 10 through 25 years of age enrolled in these clinical studies 6.4% of  
167 subjects who received CERVARIX and 7.2% of subjects who received the control reported at  
168 least one serious adverse event during the entire follow-up period (up to 7.4 years).

169 **Deaths:** In completed and ongoing studies which enrolled 57,323 females 9 through 72  
170 years of age, 37 deaths were reported during the 7.4 years of follow-up: 20 in subjects who  
171 received CERVARIX (0.06%, 20/33,623) and 17 in subjects who received control (0.07%,  
172 17/23,700). Causes of death among subjects were consistent with those reported in adolescent  
173 and adult female populations. The most common causes of death were motor vehicle accident (5  
174 subjects who received CERVARIX; 5 subjects who received control) and suicide (2 subjects  
175 who received CERVARIX; 5 subjects who received control), followed by neoplasm (3 subjects  
176 who received CERVARIX; 2 subjects who received control), autoimmune disease (3 subjects  
177 who received CERVARIX; 1 subject who received control), infectious disease (3 subjects who  
178 received CERVARIX; 1 subject who received control), homicide (2 subjects who received  
179 CERVARIX; 1 subject who received control), cardiovascular disorders (2 subjects who received  
180 CERVARIX), and death of unknown cause (2 subjects who received control). Among females  
181 10 through 25 years of age, 31 deaths were reported (0.05%, 16/29,467 of subjects who received  
182 CERVARIX and 0.07%, 15/20,192 of subjects who received control).

## 183 **6.2 Postmarketing Experience**

184 In addition to reports in clinical trials, worldwide voluntary reports of adverse events  
185 received for CERVARIX since market introduction (2007) are listed below. This list includes  
186 serious events or events which have suspected causal association to CERVARIX. Because these  
187 events are reported voluntarily from a population of uncertain size, it is not always possible to  
188 reliably estimate their frequency or establish a causal relationship to vaccination.

189 **Immune System Disorders:** Allergic reactions (including anaphylactic and  
190 anaphylactoid reactions), angioedema, erythema multiforme.

191 **Nervous System Disorders:** Syncope or vasovagal responses to injection (sometimes  
192 accompanied by tonic-clonic movements).

## 193 **7 DRUG INTERACTIONS**

### 194 **7.1 Concomitant Vaccine Administration**

195 There are no data to assess the concomitant use of CERVARIX with other vaccines.

196 Do not mix CERVARIX with any other vaccine in the same syringe or vial.



197 **7.2 Hormonal Contraceptives**

198 Among 7,693 subjects 15 through 25 years of age in Study 2 (CERVARIX, N = 3,821 or  
199 Hepatitis A Vaccine 720 EL.U., N = 3,872) who used hormonal contraceptives for a mean of 2.8  
200 years, the observed efficacy of CERVARIX was similar to that observed among subjects who  
201 did not report use of hormonal contraceptives.

202 **7.3 Immunosuppressive Therapies**

203 Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents,  
204 cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the  
205 immune response to CERVARIX [see *Use in Specific Populations* (8.6)].

206 **8 USE IN SPECIFIC POPULATIONS**

207 **8.1 Pregnancy**

208 **Pregnancy Category B**

209 Reproduction studies have been performed in rats at a dose approximately 47 times the  
210 human dose (on a mg/kg basis) and revealed no evidence of impaired fertility or harm to the  
211 fetus due to CERVARIX. There are, however, no adequate and well-controlled studies in  
212 pregnant women. Because animal reproduction studies are not always predictive of human  
213 response, this drug should be used during pregnancy only if clearly needed.

214 Non-Clinical Studies: An evaluation of the effect of CERVARIX on embryo-fetal, pre-  
215 and post-natal development was conducted using rats. One group of rats was administered  
216 CERVARIX 30 days prior to gestation and during the period of organogenesis (gestation days 6,  
217 8, 11, and 15). A second group of rats was administered saline at 30 days prior to gestation  
218 followed by CERVARIX on days 6, 8, 11, and 15 of gestation. Two additional groups of rats  
219 received either saline or adjuvant following the same dosing regimen. CERVARIX was  
220 administered at 0.1 mL/rat/occasion (approximately 47-fold excess relative to the projected  
221 human dose on a mg/kg basis) by intramuscular injection. No adverse effects on mating, fertility,  
222 pregnancy, parturition, lactation, or embryo-fetal, pre- and post-natal development were  
223 observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis.

224 Clinical Studies: Overall Outcomes: In clinical studies, pregnancy testing was  
225 performed prior to each vaccine administration and vaccination was discontinued if a subject had  
226 a positive pregnancy test. In all clinical trials, subjects were instructed to take precautions to  
227 avoid pregnancy until 2 months after the last vaccination. During pre-licensure clinical  
228 development, a total of 7,276 pregnancies were reported among 3,696 females receiving  
229 CERVARIX and 3,580 females receiving a control (Hepatitis A Vaccine 360 EL.U., Hepatitis A  
230 Vaccine 720 EL.U., or 500 mcg Al(OH)<sub>3</sub>). The overall proportions of pregnancy outcomes were  
231 similar between treatment groups. The majority of women gave birth to normal infants (62.2%  
232 and 62.6% of recipients of CERVARIX and control, respectively). Other outcomes included  
233 spontaneous abortion (11.0% and 10.8% of recipients of CERVARIX and control, respectively),  
234 elective termination (5.8% and 6.1% of recipients of CERVARIX and control, respectively),  
235 abnormal infant other than congenital anomaly (2.8% and 3.2% of recipients of CERVARIX and

control, respectively), and premature birth (2.0% and 1.7% of recipients of CERVARIX and control, respectively). Other outcomes (congenital anomaly, stillbirth, ectopic pregnancy, and therapeutic abortion) were reported less frequently in 0.1% to 0.8% of pregnancies in both groups.

**Outcomes Around Time of Vaccination:** Sub-analyses were conducted to describe pregnancy outcomes in 761 women [N = 396 for CERVARIX and N = 365 pooled control, HAV 360 EL.U., HAV 720 EL.U. and 500 mcg Al(OH)<sub>3</sub>] who had their last menstrual period within 30 days prior to, or 45 days after a vaccine dose and for whom pregnancy outcome was known. The majority of women gave birth to normal infants (65.2% and 69.3% of recipients of CERVARIX and control, respectively). Spontaneous abortion was reported in a total of 11.7% of subjects (13.6% of recipients of CERVARIX and 9.6% of control recipients) and elective termination was reported in a total of 9.7% of subjects (9.9% of recipients of CERVARIX and 9.6% of control recipients). Abnormal infant other than congenital anomaly was reported in a total of 4.9% of subjects (5.1% of recipients of CERVARIX and 4.7% of control recipients) and premature birth was reported in a total of 2.5% of subjects (2.5% of both groups). Other outcomes (congenital anomaly, stillbirth, ectopic pregnancy, and therapeutic abortion) were reported in 0.3% to 1.8% of pregnancies among recipients of CERVARIX and in 0.3% to 1.4% of pregnancies among control recipients.

It is not known whether the observed numerical imbalance in spontaneous abortions in pregnancies which occurred around the time of vaccination is due to a vaccine-related effect.

**Pregnancy Registry:** Healthcare providers are encouraged to register pregnant women who inadvertently receive CERVARIX in the GlaxoSmithKline vaccination pregnancy registry by calling 1-888-452-9622.

### **8.3 Nursing Mothers**

In non-clinical studies in rats, serological data suggest a transfer of anti-HPV-16 and anti-HPV-18 antibodies via milk during lactation in rats. Excretion of vaccine-induced antibodies in human milk has not been studied for CERVARIX. Because many drugs are excreted in human milk, caution should be exercised when CERVARIX is administered to a nursing woman.

### **8.4 Pediatric Use**

Safety and effectiveness in pediatric patients younger than 10 years of age have not been established. The safety and effectiveness of CERVARIX have been evaluated in 1,193 subjects 10 through 14 years of age and 6,316 subjects 15 through 17 years of age. [See *Adverse Reactions (6.1) and Clinical Studies (14.5).*]

### **8.5 Geriatric Use**

Clinical studies of CERVARIX did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger subjects. CERVARIX is not approved for use in subjects 65 years of age and older.

### **8.6 Immunocompromised Individuals**

The immune response to CERVARIX may be diminished in immunocompromised individuals [see *Drug Interactions (7.3)*].

## 276 11 DESCRIPTION

277 CERVARIX [Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant]  
278 is a non-infectious recombinant, AS04-adjuvanted vaccine that contains recombinant L1 protein,  
279 the major antigenic protein of the capsid, of oncogenic HPV types 16 and 18. The L1 proteins  
280 are produced in separate bioreactors using the recombinant Baculovirus expression vector system  
281 in a serum-free culture media composed of chemically-defined lipids, vitamins, amino acids, and  
282 mineral salts. Following replication of the L1 encoding recombinant Baculovirus in  
283 *Trichoplusia ni* insect cells, the L1 protein accumulates in the cytoplasm of the cells. The L1  
284 proteins are released by cell disruption and purified by a series of chromatographic and filtration  
285 methods. Assembly of the L1 proteins into virus-like particles (VLPs) occurs at the end of the  
286 purification process. The purified, non-infectious VLPs are then adsorbed on to aluminum (as  
287 hydroxide salt). The adjuvant system, AS04, is composed of 3-*O*-desacyl-4'-monophosphoryl  
288 lipid A (MPL) adsorbed on to aluminum (as hydroxide salt).

289 CERVARIX is prepared by combining the adsorbed VLPs of each HPV type together  
290 with the AS04 adjuvant system in sodium chloride, sodium dihydrogen phosphate dihydrate, and  
291 Water for Injection.

292 CERVARIX is a sterile suspension for intramuscular injection. Each 0.5-mL dose is  
293 formulated to contain 20 mcg of HPV type 16 L1 protein, 20 mcg of HPV type 18 L1 protein,  
294 50 mcg of the 3-*O*-desacyl-4'-monophosphoryl lipid A (MPL), and 0.5 mg of aluminum  
295 hydroxide. Each dose also contains 4.4 mg of sodium chloride and 0.624 mg of sodium  
296 dihydrogen phosphate dihydrate. Each dose may also contain residual amounts of insect cell and  
297 viral protein (<40 ng) and bacterial cell protein (<150 ng) from the manufacturing process.  
298 CERVARIX does not contain a preservative.

## 299 12 CLINICAL PHARMACOLOGY

### 300 12.1 Mechanism of Action

301 Animal studies suggest that the efficacy of L1 VLP vaccines may be mediated by the  
302 development of IgG neutralizing antibodies directed against HPV-L1 capsid proteins generated  
303 as a result of vaccination.

## 304 13 NONCLINICAL TOXICOLOGY

### 305 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

306 CERVARIX has not been evaluated for its carcinogenic or mutagenic potential.  
307 Vaccination of female rats with CERVARIX, at doses shown to be significantly immunogenic in  
308 the rat, had no effect on fertility.

## 309 14 CLINICAL STUDIES

310 Cervical intraepithelial neoplasia (CIN) grade 2 and 3 lesions or cervical adenocarcinoma  
311 *in situ* (AIS) are the immediate and necessary precursors of squamous cell carcinoma and  
312 adenocarcinoma of the cervix, respectively. Their detection and removal has been shown to  
313 prevent cancer. Therefore, CIN2/3 and AIS (precancerous lesions) serve as surrogate markers for

the prevention of cervical cancer. In clinical studies to evaluate the efficacy of CERVARIX, the endpoints were cases of CIN2/3 and AIS associated with HPV-16, HPV-18, and other oncogenic HPV types. Persistent infection with HPV-16 and HPV-18 that lasts for 12 months was also an endpoint.

The efficacy of CERVARIX to prevent histopathologically-confirmed CIN2/3 or AIS was assessed in 2 double-blind, randomized, controlled clinical studies that enrolled a total of 19,778 females 15 through 25 years of age.

Study 1 (HPV 001) enrolled women who were negative for oncogenic HPV DNA (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) in cervical samples, seronegative for HPV-16 and HPV-18 antibodies and had normal cytology. This represents a population presumed “naïve” without current HPV infection at the time of vaccination and without prior exposure to either HPV-16 or HPV-18. Subjects were enrolled in an extended follow-up study (Study 1 extension [HPV 007]) to evaluate the long-term efficacy, immunogenicity, and safety. These subjects have been followed for up to 6.4 years.

In Study 2 (HPV 008), women were vaccinated regardless of baseline HPV DNA status, serostatus or cytology. This study reflects a population of women naïve (without current infection and without prior exposure) or non-naïve (with current infection and/or with prior exposure) to HPV. Before vaccination, cervical samples were assessed for oncogenic HPV DNA (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and serostatus of HPV-16 and HPV-18 antibodies.

In both studies, testing for oncogenic HPV types was conducted using SPF<sub>10</sub>-LiPA<sub>25</sub> PCR to detect HPV DNA in archived biopsy samples.

#### **14.1 Prophylactic Efficacy Against HPV Types 16 and 18**

Study 2: A randomized, double-blind, controlled clinical trial was conducted in which 18,665 healthy females 15 through 25 years of age received CERVARIX or Hepatitis A Vaccine control on a 0-, 1-, and 6-month schedule. Among subjects, 54.8% of subjects were white, 31.5% Asian, 7.1% Hispanic, 3.7% black, and 2.9% were of other racial/ethnic groups.

In this study, women were randomized and vaccinated regardless of baseline HPV DNA status, serostatus or cytology. Women with HPV-16 or HPV-18 DNA present in baseline cervical samples (HPV DNA positive) at study entry were considered currently infected with that specific HPV type. If HPV DNA was not detected by PCR, women were considered HPV DNA negative. Additionally, cervical samples were assessed for cytologic abnormalities and serologic testing was performed for anti-HPV-16 and anti-HPV-18 serum antibodies at baseline. Women with anti-HPV serum antibodies present were considered to have prior exposure to HPV and characterized as seropositive. Women seropositive for HPV-16 or HPV-18 but DNA negative for that specific serotype were considered as having cleared a previous natural infection. Women without antibodies to HPV-16 and HPV-18 were characterized as seronegative. Before vaccination, 73.6% of subjects were naïve (without current infection [DNA negative] and without prior exposure [seronegative]) to HPV-16 and/or HPV-18.

Efficacy endpoints included histological evaluation of precancerous and dysplastic lesions (CIN grade 1, grade 2, or grade 3), and AIS. The mean follow-up after the first dose was approximately 39 months. Virological endpoints (HPV DNA in cervical samples detected by PCR) included 12-month persistent infection (defined as at least 2 positive specimens for the same HPV type over a minimum interval of 10 months).

The according to protocol (ATP) cohort for efficacy analyses for HPV-16 and/or HPV-18 included all subjects who received 3 doses of vaccine, for whom efficacy endpoint measures were available and who were HPV-16 and/or HPV-18 DNA negative and seronegative at baseline and HPV-16 and/or HPV-18 DNA negative at month 6 for the HPV type considered in the analysis. Case counting for the ATP cohort started on day 1 after the third dose of vaccine. This cohort included women who had normal or low-grade cytology (cytological abnormalities including atypical squamous cells of undetermined significance [ASC-US] or low grade squamous intraepithelial lesions [LSIL]) at baseline and excluded women with high-grade cytology.

The total vaccinated cohort (TVC) for each efficacy analysis included all subjects who received at least one dose of the vaccine, for whom efficacy endpoint measures were available, irrespective of their HPV DNA status, cytology, and serostatus at baseline. This cohort included women with or without current HPV infection and/or prior exposure. Case counting for the TVC started on day 1 after the first dose.

The TVC naïve is a subset of the TVC that had normal cytology, and were HPV DNA negative for 14 oncogenic HPV types and seronegative for HPV-16 and HPV-18 at baseline.

CERVARIX was efficacious in the prevention of precancerous lesions or AIS associated with HPV-16 or HPV-18 (Table 5).

**Table 5. Efficacy of CERVARIX Against Histopathological Lesions Associated With HPV-16 or HPV-18 in Females 15 Through 25 Years of Age (According to Protocol Cohort<sup>a</sup>) (Study 2)**

	CERVARIX		Control <sup>b</sup>		% Efficacy (96.1% CI) <sup>c</sup>
	N	Number of Cases	N	Number of Cases	
CIN2/3 or AIS	7,344	4	7,312	56	92.9 (79.9, 98.3)
CIN1/2/3 or AIS	7,344	8	7,312	96	91.7 (82.4, 96.7)

CI = Confidence Interval.

<sup>a</sup> Subjects (including women who had normal cytology, ASC-US, or LSIL at baseline) who received 3 doses of vaccine and were HPV DNA negative and seronegative at baseline and HPV DNA negative at month 6 for the corresponding HPV type (N). The mean follow-up was approximately 35 months.

<sup>b</sup> Hepatitis A Vaccine control group [720 EL.U. of antigen and 500 mcg Al(OH)<sub>3</sub>].

386     <sup>c</sup> The 96.1% confidence interval reflected in this final analysis results from statistical  
387     adjustment for the previously conducted interim analysis.

388  
389     Since CIN3 or AIS represents a more immediate precursor to cervical cancer, cases of  
390     CIN3 or AIS associated with HPV-16 or HPV-18 were evaluated. In the ATP cohort,  
391     CERVARIX was efficacious in the prevention of CIN3 or AIS associated with HPV-16 or  
392     HPV-18 (vaccine efficacy = 80.0% [96.1% CI: 0.3, 98.1]).

393     Subjects who were already infected with one vaccine HPV type (16 or 18) prior to  
394     vaccination were protected from precancerous lesions or AIS and infection caused by the other  
395     vaccine HPV type.

396     Efficacy of CERVARIX against 12-month persistent infection with HPV-16 or HPV-18  
397     was also evaluated. In the ATP cohort, CERVARIX reduced the incidence of 12-month  
398     persistent infection with HPV-16 and/or HPV-18 by 91.2% (96.1% CI: 85.9, 94.8).

399     Immune response following natural infection does not reliably confer protection against  
400     future infections. Among subjects who received 3 doses of CERVARIX and who were  
401     seropositive at baseline and DNA negative for HPV-16 or HPV-18 at baseline and month 6,  
402     CERVARIX reduced the incidence of 12-month persistent infection by 91.5% (96.1% CI: 64.0,  
403     99.2%). However, the number of cases of CIN2/3 or AIS was too few to determine efficacy  
404     against histopathological endpoints in this population.

405     Study 1 and Study 1 Extension: In a second double-blind, randomized, controlled  
406     study (Study 1), the efficacy of CERVARIX in the prevention of HPV-16 or HPV-18 incident  
407     and persistent infections was compared with aluminum hydroxide control in 1,113 females 15  
408     through 25 years of age. The population was naïve to current oncogenic HPV infection or prior  
409     exposure to HPV-16 and HPV-18 at the time of vaccination (total cohort). A total of 776 subjects  
410     were enrolled in the extended follow-up study (Study 1 Extension) to evaluate the long-term  
411     efficacy, immunogenicity, and safety of CERVARIX. These subjects have been followed for up  
412     to 6.4 years.

413     In Study 1 and Study 1 Extension, with up to 6.4 years of follow-up (mean 5.9 years), in  
414     naïve females 15 through 25 years of age, efficacy against CIN2/3 or AIS associated with  
415     HPV-16 or HPV-18 was 100% (98.67% CI: 28.4, 100). Efficacy against 12-month persistent  
416     infection with HPV-16 or HPV-18 was 100% (98.67% CI: 74.4, 100). The confidence interval  
417     reflected in this final analysis results from statistical adjustment for analyses previously  
418     conducted.

#### 419     **14.2 Efficacy Against HPV Types 16 and 18, Regardless of Current Infection or** 420     **Prior Exposure to HPV-16 or HPV-18**

421     Study 2: The study included women regardless of HPV DNA status (current infection)  
422     and serostatus (prior exposure) to vaccine types, HPV-16 or HPV-18 at baseline. Efficacy  
423     analyses included lesions arising among women regardless of baseline DNA status and  
424     serostatus, including HPV infections present at first vaccination and those from infections  
425     acquired after dose 1. In this population which includes naïve (without current infection and

prior exposure) and non-naïve women, CERVARIX was efficacious in the prevention of precancerous lesions or AIS associated with HPV-16 or HPV-18 (Table 6).

However, among women HPV DNA positive regardless of serostatus at baseline, there was no clear evidence of efficacy against precancerous lesions or AIS associated with HPV-16 or HPV-18 (Table 6).

**Table 6. Efficacy of CERVARIX Against Disease Associated With HPV-16 or HPV-18 in Females 15 Through 25 Years of Age, Regardless of Current or Prior Exposure to Vaccine HPV Types (Study 2)**

HPV Types (Study 2)	CERVARIX		Control		% Efficacy (96.1% CI) <sup>b</sup>
	N	Number of Cases <sup>a</sup>	N	Number of Cases <sup>a</sup>	
CIN1/2/3 or AIS					
Prophylactic Efficacy <sup>c</sup>	5,449	3	5,436	85	96.5 (89.0, 99.4)
HPV-16 or HPV-18 DNA Positive at Baseline <sup>d</sup>	641	90	592	92	--
Regardless of Current Infection or Prior Exposure to HPV-16 or HPV-18 <sup>e</sup>	8,667	107	8,682	240	55.5 <sup>f</sup> (43.2, 65.3)
CIN2/3 or AIS					
Prophylactic Efficacy <sup>c</sup>	5,449	1	5,436	63	98.4 (90.4, 100)
HPV-16 or HPV-18 DNA Positive at Baseline <sup>d</sup>	641	74	592	73	--
Regardless of Current Infection or Prior Exposure to HPV-16 or HPV-18 <sup>e</sup>	8,667	82	8,682	174	52.8 <sup>f</sup> (37.5, 64.7)
CIN3 or AIS					
Prophylactic Efficacy <sup>c</sup>	5,449	0	5,436	13	100 (64.7, 100)
HPV-16 or HPV-18 DNA Positive at Baseline <sup>d</sup>	641	41	592	38	--
Regardless of Current Infection or Prior Exposure to HPV-16 or HPV-18 <sup>e</sup>	8,667	43	8,682	65	33.6 <sup>f</sup> (-1.1, 56.9)

CI = Confidence Interval.

Table does not include disease due to non-vaccine HPV types.

<sup>a</sup> Cases = Histopathological cases associated with HPV-16 and/or HPV-18.

<sup>b</sup> The 96.1% confidence interval reflected in this final analysis results from statistical adjustment for the previously conducted interim analysis.

- 440 <sup>c</sup> TVC naïve: includes all vaccinated subjects (who received at least one dose of vaccine) who  
441 had normal cytology, were HPV DNA negative for 14 oncogenic HPV types and seronegative  
442 for HPV-16 and HPV-18 at baseline (N). Case counting started on day 1 after the first dose.  
443 <sup>d</sup> TVC subset: includes all vaccinated subjects (who received at least one dose of vaccine) who  
444 were HPV DNA positive for HPV-16 or HPV-18 irrespective of serostatus at baseline (N).  
445 Case counting started on day 1 after the first dose.  
446 <sup>e</sup> TVC: includes all vaccinated subjects (who received at least one dose of vaccine) irrespective  
447 of HPV DNA status and serostatus at baseline (N). Case counting started on day 1 after the  
448 first dose.  
449 <sup>f</sup> Observed vaccine efficacy includes the prophylactic efficacy of CERVARIX and the impact  
450 of CERVARIX on the course of infections present at first vaccination.

451

### 452 **14.3 Efficacy Against Cervical Disease Irrespective of HPV Type, Regardless of** 453 **Current or Prior Infection with Vaccine or Non-Vaccine HPV Types**

454 Study 2: The impact of CERVARIX against the overall burden of HPV-related cervical  
455 disease results from a combination of prophylactic efficacy against, and disease contribution of,  
456 HPV-16, HPV-18, and non-vaccine HPV types.

457 In the population naïve to oncogenic HPV (TVC naïve), CERVARIX reduced the overall  
458 incidence of CIN1/2/3 or AIS, CIN2/3 or AIS, and CIN3 or AIS regardless of the HPV DNA  
459 type in the lesion (Table 7). In the population of women naïve and non-naïve (TVC), vaccine  
460 efficacy against CIN1/2/3 or AIS, CIN2/3 or AIS, and CIN3 or AIS was demonstrated in all  
461 women regardless of HPV DNA type in the lesion (Table 7).

462



463 **Table 7. Efficacy of CERVARIX in Prevention of CIN or AIS Irrespective of Any HPV**  
464 **Type in Females 15 Through 25 Years of Age, Regardless of Current or Prior Infection**  
465 **with Vaccine or Non-Vaccine Types (Study 2)**

	CERVARIX		Control		% Efficacy (96.1% CI) <sup>a</sup>
	N	Number of Cases	N	Number of Cases	
<b>CIN1/2/3 or AIS</b>					
Prophylactic Efficacy <sup>b</sup>	5,449	106	5,436	211	50.1 (35.9, 61.4)
Irrespective of HPV DNA at Baseline <sup>c</sup>	8,667	451	8,682	577	21.7 (10.7, 31.4)
<b>CIN2/3 or AIS</b>					
Prophylactic Efficacy <sup>b</sup>	5,449	33	5,436	110	70.2 (54.7, 80.9)
Irrespective of HPV DNA at Baseline <sup>c</sup>	8,667	224	8,682	322	30.4 (16.4, 42.1)
<b>CIN3 or AIS</b>					
Prophylactic Efficacy <sup>b</sup>	5,449	3	5,436	23	87.0 (54.9, 97.7)
Irrespective of HPV DNA at Baseline <sup>c</sup>	8,667	77	8,682	116	33.4 (9.1, 51.5)

466 CI = Confidence Interval.

467 <sup>a</sup> The 96.1% confidence interval reflected in this final analysis results from statistical  
468 adjustment for the previously conducted interim analysis.

469 <sup>b</sup> TVC naïve: includes all vaccinated subjects (who received at least one dose of vaccine) who  
470 had normal cytology, were HPV DNA negative for 14 oncogenic HPV types (including  
471 HPV-16 and HPV-18) and seronegative for HPV-16 and HPV-18 at baseline (N). Case  
472 counting started on day 1 after the first dose.

473 <sup>c</sup> TVC: includes all vaccinated subjects (who received at least one dose of vaccine) irrespective  
474 of HPV DNA status and serostatus at baseline (N). Case counting started on day 1 after the  
475 first dose.

476  
477 In exploratory analyses, CERVARIX reduced definitive cervical therapy procedures  
478 (includes loop electrosurgical excision procedure [LEEP], cold-knife Cone, and laser procedures)  
479 by 24.7% (96.1% CI: 7.4, 38.9) in the TVC and by 68.8% (96.1% CI: 50.0, 81.2) in the TVC  
480 naïve.

481 To assess reductions in disease caused by non-vaccine HPV types, two analyses were  
482 conducted combining 12 non-vaccine oncogenic HPV types, including and excluding lesions in  
483 which HPV-16 or HPV-18 were also detected. In these analyses, among females who received 3  
484 doses of CERVARIX and were DNA negative for the specific HPV type at baseline and month

485 6), CERVARIX reduced the incidence of CIN2/3 or AIS by 54.0% (96.1% CI: 34.0, 68.4) and  
486 37.4% (96.1% CI: 7.4, 58.2), respectively.

487 Post-hoc analyses, adjusted for multiplicity, were conducted to assess the impact of  
488 CERVARIX on CIN2/3 or AIS due to specific non-vaccine HPV types. The ATP cohort for  
489 these analyses included all subjects irrespective of serostatus who received 3 doses of  
490 CERVARIX and were DNA negative for the specific HPV type at baseline and month 6. These  
491 post-hoc analyses were also conducted in the TVC naïve population. In analyses including  
492 lesions in which HPV-16 or HPV-18 were also detected, vaccine efficacy in prevention of  
493 CIN2/3 or AIS associated with HPV-31 was 92.0% (99.7% CI: 49.0, 99.8) and 100% (99.7% CI:  
494 62.3, 100), respectively. In analyses excluding lesions in which HPV-16 or HPV-18 were  
495 detected, vaccine efficacy in prevention of CIN2/3 or AIS associated with HPV-31 was 89.4%  
496 (99.7% CI: 29.0, 99.7) and 100% (99.7% CI: 36.3, 100), respectively.

#### 497 **14.4 Immunogenicity**

498 The minimum anti-HPV titer that confers protective efficacy has not been determined.

499 The antibody response to HPV-16 and HPV-18 was measured using a type-specific  
500 binding ELISA (developed by GlaxoSmithKline) and a pseudovirion-based neutralization assay  
501 (PBNA). In a subset of subjects tested for HPV-16 and HPV-18, the ELISA has been shown to  
502 correlate with the PBNA. The scales for these assays are unique to each HPV type and each  
503 assay, thus, comparison between HPV types or assays is not appropriate.

504 Duration of Immune Response: The duration of immunity following a complete  
505 schedule of immunization with CERVARIX has not been established. In Study 1 and Study 1  
506 Extension, the immune response against HPV-16 and HPV-18 was evaluated for up to 76 months  
507 post-dose 1, in females 15 through 25 years of age. Vaccine-induced geometric mean titers  
508 (GMTs) for both HPV-16 and HPV-18 peaked at month 7 and thereafter reached a plateau that  
509 was sustained from month 18 up to month 76. At all timepoints, >98% of subjects were  
510 seropositive for both HPV-16 ( $\geq 8$  EL.U./mL, the limit of detection) and HPV-18 ( $\geq 7$  EL.U./mL,  
511 the limit of detection) by ELISA.

512 In Study 2, GMTs for ELISA and PBNA one month post-dose 3 were measured  
513 (Table 8). The ATP cohort for immunogenicity included all evaluable subjects for whom data  
514 concerning immunogenicity endpoint measures were available. These included subjects for  
515 whom assay results were available for antibodies against at least one vaccine type. Subjects who  
516 acquired either HPV-16 or HPV-18 infection during the trial were excluded. Of subjects  
517 seronegative at baseline, 99.5% were seropositive for anti-HPV-16 and anti-HPV-18 antibodies  
518 at month 7 post-vaccination.

519

**Table 8. Summary of Anti-HPV Geometric Mean Titers (GMTs) for HPV-16 and HPV-18 at Month 7 for Initially Seronegative Females 15 Through 25 Years of Age (According to Protocol Cohort for Immunogenicity<sup>a</sup>) (Study 2)**

Antibody Assay	N	CERVARIX GMT (95% CI)	N	Control GMT (95% CI)
<b>ELISA<sup>b</sup> (EL.U./mL)</b>				
Anti-HPV-16	861	9,206.4 (8,607.2, 9,847.2)	738	4.4 (4.2, 4.6)
Anti-HPV-18	924	4,744.6 (4,454.1, 5,053.9)	769	3.8 (3.6, 3.9)
<b>PBNA<sup>c</sup> (ED<sub>50</sub>)</b>				
Anti-HPV-16	46	27,364.8 (19,780.1, 37,857.9)	44	20.0 (20.0, 20.0)
Anti-HPV-18	46	9,052 (6,851.8, 11,960.5)	44	20.0 (20.0, 20.0)

<sup>a</sup> Subjects who received 3 doses of vaccine for whom assay results were available for at least one post-vaccination antibody measurement (N). Subjects who acquired either HPV-16 or HPV-18 infection during the study were excluded.

<sup>b</sup> Enzyme linked immunosorbent assay (assay cut-off 8 EL.U./mL for anti-HPV-16 antibody and 7 EL.U./mL for anti-HPV-18 antibody).

<sup>c</sup> Pseudovirion-based neutralization assay (assay cut-off 40 ED<sub>50</sub> for both anti-HPV-16 antibody and anti-HPV-18 antibody).

#### **14.5 Bridging of Efficacy from Women to Adolescent Girls**

The immunogenicity of CERVARIX was evaluated in 2 clinical studies involving 1,193 girls 10 through 14 years of age who received CERVARIX.

Study 3 (HPV 013) was a double-blind, randomized, controlled study in which 1,035 subjects received CERVARIX and 1,032 subjects received a Hepatitis A Vaccine 360 EL.U. as the control vaccine with a subset of subjects evaluated for immunogenicity. All initially seronegative subjects in the group who received CERVARIX were seropositive after vaccination, i.e. had levels of antibody greater than the limit of detection of the assay to both HPV-16 ( $\geq 8$  EL.U./mL) and HPV-18 ( $\geq 7$  EL.U./mL) antigens. The GMTs for anti-HPV-16 and anti-HPV-18 antibodies in initially seronegative subjects are presented in Table 9.

542 **Table 9. Geometric Mean Titers (GMTs) at Months 7 and 18 for Initially Seronegative**  
543 **Females 10 Through 14 Years of Age (According To Protocol Cohort for Immunogenicity<sup>a</sup>)**  
544 **(Study 3)**

Age Group	Anti-HPV-16 Antibodies GMT EL.U/mL (95% CI)			Anti-HPV-18 Antibodies GMT EL.U/mL (95% CI)		
	N	Month 7	Month 18	N	Month 7	Month 18
10-14 years of age	556-619	19,882.0 (18,626.7, 21,221.9)	3,888.8 (3,605.0, 4,195.0)	562-628	8,262.0 (7,725.0, 8,836.2)	1,539.4 (1,418.8, 1,670.3)

545 <sup>a</sup> Subjects who received 3 doses of vaccine for whom assay results were available for at least  
546 one post-vaccination antibody measurement (N).  
547

548 In Study 4 (HPV 012), the immunogenicity of CERVARIX administered to girls 10  
549 through 14 years of age was compared to that in females 15 through 25 years of age. The  
550 immune response in girls 10 through 14 years of age measured one month post-dose 3 was non-  
551 inferior to that seen in females 15 through 25 years of age for both HPV-16 and HPV-18  
552 antigens (Table 10).  
553

554 **Table 10. Geometric Mean Titers (GMTs) and Seropositivity Rates at Month 7 for Initially**  
555 **Seronegative Females 10 Through 14 Years of Age Compared to 15 Through 25 Years of**  
556 **Age (According To Protocol Cohort for Immunogenicity<sup>a</sup>) (Study 4)**

Antibody Assay	10-14 Years of Age			15-25 Years of Age		
	N	GMT <sup>b</sup> EL.U/mL (95% CI)	Seropositivity Rate <sup>c</sup> %	N	GMT <sup>b</sup> EL.U/mL (95% CI)	Seropositivity Rate <sup>c</sup> %
Anti-HPV-16	143	17,272.5 (15,117.9, 19,734.1)	100	118	7,438.9 (6,324.6, 8,749.6)	100
Anti-HPV-18	141	6,863.8 (5,976.3, 7,883.0)	100	116	3,070.1 (2,600.0, 3,625.4)	100

557 <sup>a</sup> Subjects who received 3 doses of vaccine for whom assay results were available for at least  
558 one post-vaccination antibody measurement (N).  
559

559 <sup>b</sup> Non-inferiority based on the upper limit of the 2-sided 95% CI for the GMT ratio (15-25 year  
560 olds/10-14 year olds) was <2.  
561

561 <sup>c</sup> Non-inferiority based on the upper limit of the 2-sided 95% CI for the difference between the  
562 seropositivity rates for 10-14 year olds and 15-25 year olds was <10%.  
563

564 Based on these immunogenicity data, the efficacy of CERVARIX is inferred in girls 10  
565 through 14 years of age.

## 566 **16 HOW SUPPLIED/STORAGE AND HANDLING**

567 CERVARIX is available in 0.5-mL single-dose vials and prefilled TIP-LOK syringes.

568           Single-Dose Vials  
569   NDC 58160-830-11 (package of 10)  
570           Single-Dose Prefilled Disposable TIP-LOK Syringes (packaged without needles)  
571   NDC 58160-830-32 (package of 1)  
572   NDC 58160-830-46 (package of 5)  
573           Store refrigerated between 2° and 8°C (36° and 46°F). Do not freeze. Discard if the  
574   vaccine has been frozen. Upon storage, a fine, white deposit with a clear, colorless supernatant  
575   may be observed. This does not constitute a sign of deterioration.

576   **17   PATIENT COUNSELING INFORMATION**

577           Provide the Vaccine Information Statements prior to immunization. (This is required by  
578   the National Childhood Vaccine Injury Act of 1986 and are available free of charge at the  
579   Centers for Disease Control and Prevention (CDC) website ([www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)).

580           Inform the patient, parent, or guardian:

- 581   • Vaccination does not substitute for routine cervical cancer screening. Women who receive  
582   CERVARIX should continue to undergo cervical cancer screening per standard of care.
- 583   • CERVARIX does not protect against disease from HPV types to which a woman has  
584   previously been exposed through sexual activity.
- 585   • Since syncope has been reported following vaccination in young females, sometimes  
586   resulting in falling with injury, observation for 15 minutes after administration is  
587   recommended.
- 588   • Information regarding potential benefits and risks associated with vaccination.
- 589   • Report any adverse events to their healthcare provider.
- 590   • Safety has not been established in pregnant women. CERVARIX is not recommended for use  
591   in pregnant women or women planning to become pregnant during the vaccination course.  
592   Register women who receive CERVARIX while pregnant in the pregnancy registry by  
593   calling 1-888-452-9622.

594

595   CERVARIX and TIP-LOK are registered trademarks of GlaxoSmithKline.

596



597  
598   Manufactured by **GlaxoSmithKline Biologicals**  
599   Rixensart, Belgium, US License 1617  
600   Distributed by **GlaxoSmithKline**  
601   Research Triangle Park, NC 27709  
602  
603   ©YEAR, GlaxoSmithKline. All rights reserved.

## EXHIBIT 3

## Vaccines, Blood & Biologics

### October 16, 2009 Approval Letter - Cervarix

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug  
Administration  
Rockville, MD 20852-  
1448

Our STN: BL 125259/0

GlaxoSmithKline Biologicals  
Attention: Matthew Whitman  
2301 Renaissance Boulevard  
P.O. Box 61540  
King of Prussia, PA 19406-2772

Dear Mr. Whitman:

We have approved your biologics license application for Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant, effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant under your existing Department of Health and Human Services U.S. License No. 1617. Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant is indicated for the prevention of cervical cancer, cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma in situ, and cervical intraepithelial neoplasia (CIN) grade 1, caused by oncogenic human papillomavirus (HPV) types 16 and 18, in females 10 through 25 years of age.

Under this license, you are approved to manufacture Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant. The drug substance will be manufactured at GlaxoSmithKline Biologicals in ----b(4)----- . The final product will be formulated at Rixensart, Belgium, filled at Rixensart and --b(4)-- , and labeled and packaged at --b(4)-- . You may label your product with the proprietary name CERVARIX®. The vaccine will be supplied in 0.5 mL single dose vials and 0.5 mL single dose prefilled TIP-LOK® syringes.

The dating period for Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant (CERVARIX) shall be 36 months from the date of manufacture when stored at 2°C to 8°C.

The date of manufacture shall be defined as the start date of filling into final containers.

-----b(4)-----  
-----

Please submit final container samples of the product together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

You must submit information to your biologics license application for our review and written approval under 21 CFR 601.12 for any changes in the manufacturing, testing, packaging or labeling of CERVARIX or in the manufacturing facilities.

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution in a timely manner. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Rockville, MD 20852-1448.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h and FDA Form 2567 as appropriate. Please provide content of labeling in Structured Product Labeling format.

In addition, you may wish to submit two draft copies of the proposed introductory advertising and promotional labeling with a Form FDA 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Please submit your final printed advertising and promotional labeling at the time of initial dissemination, accompanied by Form FDA 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have submitted data to support such claims for review and approval by CBER.

## **ADVERSE EVENT REPORTING**

Adverse experience reports should be submitted, at minimum, in accordance with the adverse experience reporting requirements for licensed biological products (21



CFR 600.80). Individual adverse event reports should be submitted to the Vaccine Adverse Event Reporting System (VAERS) electronically at <https://secure.vaers.org/VaersDataEntryintro.htm> or by mail to P.O. Box 1100, Rockville, MD 20849-1100, using the pre-addressed form VAERS-1 available at the VAERS website (<http://vaers.hhs.gov>). Distribution reports should be submitted on a monthly basis for the first year after market introduction and then at least every six months in accordance with 21 CFR 600.81. Under 21 CFR 600.80(c)(2) [Periodic Adverse Experience Reports], you must report each adverse experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals for the first 3 years following approval, and then at annual intervals.

## **PEDIATRIC REQUIREMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric study for CERVARIX, in females 9 years of age, until June 30, 2010, because the data support approval of this product for use in females 10 through 25 years of age, and this pediatric study has not been completed.

Your deferred pediatric study required under 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study must be reported according to 21 CFR 601.70 and Section 505B(a)(3)(B) of the FDCA. This required study is listed below:

1. A clinical study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant when administered to healthy females 9 through 25 years of age.

We acknowledge your September 16, 2009, commitment to submit the final clinical study report by June 30, 2010.

Please submit the final clinical study report to this BLA (STN 125259). For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated **"Required Pediatric Assessment."**

We are waiving the pediatric study requirement for children from 0 through 8 years of age because the necessary studies are impossible or highly impracticable as there are too few children with the disease/condition to study.

We note that you have fulfilled the pediatric study requirement for children 10 through 16 years of age with this application.

### **POSTMARKETING REQUIREMENTS UNDER 505(o)**

Section 505(o) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (Section 505(o)(3)(A)).

FDA has determined that you are required to conduct a postmarketing study pursuant to Section 505(o)(3)(B)(iii) of the FDCA based upon a subgroup analysis of clinical trial data suggesting a numerical imbalance in spontaneous abortions among CERVARIX recipients whose pregnancies occurred around the time of vaccination (defined as the last menstrual period occurring 30 days before until 45 days after vaccination), compared to control subjects.

We have determined that an analysis of spontaneously reported adverse events, after product licensure, pursuant to subsection 505(k)(1) of the FDCA, will not be sufficient to identify an unexpected serious risk when available data indicates such potential.

Therefore, you are required to conduct a post-licensure analytic epidemiologic study to assess the risk of spontaneous abortion following CERVARIX vaccination as outlined below:

2. To conduct a post-licensure analytic epidemiologic study to assess the risk of spontaneous abortion following administration of CERVARIX to women who become pregnant shortly after vaccination and in women who inadvertently received CERVARIX prior to knowledge of their pregnancy.

We acknowledge the timetable you submitted on September 24, 2009, which states that you will conduct this trial according to the following schedule: The draft protocol will be submitted by December 31, 2009, and the final protocol by April 30, 2010. Study initiation will occur 6 to 12 months after final protocol submission. The anticipated study completion date will be when subject enrollment is sufficient to detect an increased relative risk of approximately 2.0 for spontaneous abortions if it exists. The final clinical study report will be submitted within 6 months after study completion. Interim reports will be submitted to the FDA every 6 months for the duration of the study.

Please submit the study protocol to your IND -b(4)-, with a cross-reference letter to this BLA, and submit all final reports to this BLA. Please submit a supplement, reflecting the results of the study, and use the following designators to prominently label all submissions, including supplements, relating to this postmarketing study requirement as appropriate:

- **Required Postmarketing Study Protocol under 505(o)**
- **Required Postmarketing Study Final Report under 505(o)**
- **Required Postmarketing Study Correspondence under 505(o)**
- **Required Postmarketing Study 6-Month Interim Report under 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B of the FDCA, as well as 21 CFR 601.70, requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report, under Section 506B and

21 CFR 601.70, to satisfy the periodic reporting requirement under Section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 601.70. We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA Section 505(o)(3)(E)(ii) and could result in enforcement action.

#### **AGREED UPON POSTMARKETING COMMITMENTS**

##### **Postmarketing study subject to reporting requirements of 21 CFR 601.70**

We acknowledge your written commitments as described in your correspondence and submissions of July 31, August 14, September 21, and October 2, October 7, and

October 9, 2009, as outlined below:

3. To conduct an observational study in a U.S. managed care organization to evaluate the incidence of new onset autoimmune disease among at least 50,000 CERVARIX recipients. The final protocol will be submitted by March 2010. Projected completion of patient accrual, subject to vaccine uptake, will be completed by March 2013. Projected study completion, subject to vaccine uptake, will be completed by September 2014. The final study report is projected to be submitted by March 2015 (6 months after study completion).
4. To establish a U.S. pregnancy registry. The registry will be initiated immediately after vaccine licensure and continue for at least 5 years. Supplemental data from an ongoing pregnancy registry in the United Kingdom, operated by the Health Protection Agency, will be included in all

GSK analyses submitted to FDA.

5. To submit final study reports for the following on-going long term efficacy studies:

- a. Study HPV-008: This study will be completed by October 30, 2009. The final clinical study report will be submitted by December 31, 2010.
- b. Study HPV-009: This study will be completed by October 30, 2010. The final clinical study report will be submitted by January 31, 2012.
- c. Study HPV-015: This study will be completed by October 30, 2010. The final clinical study report will be submitted by December 31, 2011.
- d. Study HPV-023: This study will be completed by September 30, 2010. The final clinical study report will be submitted by September 30, 2011.
- e. Study HPV-024: This study has been completed. The final clinical study report will be submitted by December 31, 2009.
- f. Study HPV-040: The final protocol will be submitted by December 1, 2009. Subject accrual will be completed on December 31, 2009. This study will be completed by June 30, 2014. The final clinical study report will be submitted by December 31, 2015.

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment
- the original schedule for the commitment
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted)
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment)

Please submit clinical protocols to your IND -b(4)-, with a cross-reference letter to this BLA. Submit chemistry, manufacturing, and controls protocols and final study reports to this BLA. If the information in the final study report supports a change in the labeling, the final study report should be submitted as a supplement. We may also request a supplement if we think labeling changes are needed. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Study Protocol**
- **Postmarketing Study Final Report**
- **Postmarketing Study Correspondence**
- **Annual Report on Postmarketing Studies**

When you have fulfilled your commitment, submit your final report as "PMC Submission – Final Study Report" or "Supplement Contains Postmarketing Study Commitment – Final Study Report."

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site  
<http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm>.

Please refer to FDA's Guidance for Industry: Reports on the Status of Postmarketing Commitments - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 for further information.

**Postmarketing Studies not subject to reporting requirements of 21 CFR 601.70.**

We acknowledge your written commitments as described in your correspondence of

October 2 and October 8, 2009, as outlined below:

6. -----b(4)-----  
-----  
-----  
-----  
-----  
-----  
-----
7. -----b(4)-----  
-----

For each postmarketing commitment not subject to the reporting requirements of 21 CFR 601.70, you may report the status to FDA as a "PMC Submission – Status Update." The status report for each commitment should include:

- Information to identify and describe the postmarketing commitment,
- The original schedule for the commitment,
- The status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted),
- An explanation of the status including, for clinical studies, the subject accrual rate (i.e., number enrolled to data and the total planned enrollment).

If you have any questions, please contact Ms. Helen S. Gemignani, Regulatory Project Manager, at 301-827-3070.

Sincerely yours,

--signature--

Norman W. Baylor, Ph.D.  
Director  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research

## Contact Us

- **Consumer Affairs Branch (CBER)**

- (800) 835-4709
- (301) 827-1800
- [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov)

Division of Communication and Consumer Affairs

Office of Communication, Outreach and Development

Food and Drug Administration

1401 Rockville Pike

Suite 200N/HFM-47

Rockville, MD 20852-1448

## EXHIBIT 4



US007351533B2

(12) **United States Patent**  
**McCarthy et al.**

(10) **Patent No.:** **US 7,351,533 B2**  
(45) **Date of Patent:** **\*Apr. 1, 2008**

(54) **IN VITRO METHOD FOR  
DISASSEMBLY/REASSEMBLY OF  
PAPILLOMAVIRUS VIRUS-LIKE PARTICLES  
(VLPs). HOMOGENEOUS VLP AND  
CAVSOMERE COMPOSITIONS PRODUCED  
BY SAID METHODS: USE THEREOF AS  
VEHICLE FOR IMPROVED PURIFICATION,  
AND DELIVERY OF ACTIVE AGENTS**

(75) **Inventors:** **Michael P. McCarthy**, Poolesville, MD  
(US); **JoAnne A. Suzich**, Washington  
Grove, MD (US)

(73) **Assignee:** **Medimmune, Inc.**, Gaithersburg, MD  
(US)

(\*) **Notice:** Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 146 days.

This patent is subject to a terminal dis-  
claimer.

(21) **Appl. No.:** **10/762,928**

(22) **Filed:** **Jan. 22, 2004**

(65) **Prior Publication Data**  
US 2004/0152181 A1 Aug. 5, 2004

#### **Related U.S. Application Data**

(60) Continuation-in-part of application No. 10/138,739,  
filed on May 6, 2002, now abandoned, and a con-  
tinuation-in-part of application No. 09/457,594, filed  
on Dec. 9, 1999, now Pat. No. 6,962,777, and a  
continuation-in-part of application No. 09/379,615,  
filed on Aug. 24, 1999, now Pat. No. 6,416,945,  
which is a division of application No. 08/923,997,  
filed on Sep. 5, 1997, now abandoned.

(51) **Int. Cl.**  
**C12Q 1/68** (2006.01)

(52) **U.S. Cl.** ..... 435/6; 435/69.1; 435/235.1  
(58) **Field of Classification Search** ..... 435/6,  
435/69.1, 235.1, 238, 239  
See application file for complete search history.

#### (56) **References Cited**

##### **U.S. PATENT DOCUMENTS**

6,066,324 A 5/2000 Gissmann et al.  
6,261,765 B1 \* 7/2001 McCarthy et al. .... 435/5  
6,416,945 B1 \* 7/2002 McCarthy et al. .... 435/5

##### **FOREIGN PATENT DOCUMENTS**

WO WO 00/57906 10/2000

##### **OTHER PUBLICATIONS**

Salunke et al. *Cell*, 1986, vol. 46, pp. 895-904.\*  
Colomar et al., *J. Virology*, vol. 67, No. 5, pp. 2779-2786 (May  
1993).  
Sapp et al., *J. Gen. Virol.*, vol. 76, pp. 2407-2412 (1995).  
Li et al., *J. Virol.*, vol. 71, No. 4, pp. 2988-2995 (Apr. 1997).  
McCarthy et al., *J. Virol.*, vol. 72, No. 1, pp. 32-41 (Jan. 1998).  
Touze et al., *Nucl. Acids Res.*, vol. 26, No. 5, pp. 1317-1323 (1998).

\* cited by examiner

*Primary Examiner*—Ali R. Salimi  
(74) *Attorney, Agent, or Firm*—Elliot M. Olstein; Raymond  
J. Lillie

#### (57) **ABSTRACT**

A method of disassembly/reassembly of papillomavirus  
VLPs is provided. The resultant VLPs have enhanced homo-  
geneity, present conformational, neutralizing PV epitopes,  
and therefore are useful prophylactic and diagnostic agents.  
Further, these VLPs can be used to encapsulate desired  
moieties, e.g., therapeutic or diagnostic agents, or marker"  
DNAs, and the resultant VLPs used as in vivo delivery  
vehicles or as pseudovirions for evaluating vaccine efficacy.

**15 Claims, 10 Drawing Sheets**



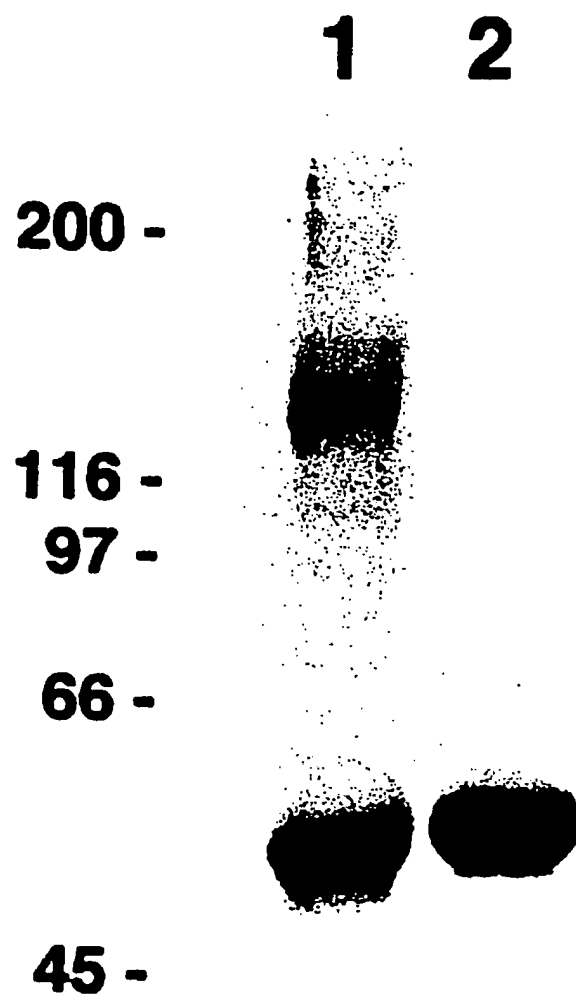


Fig. 1

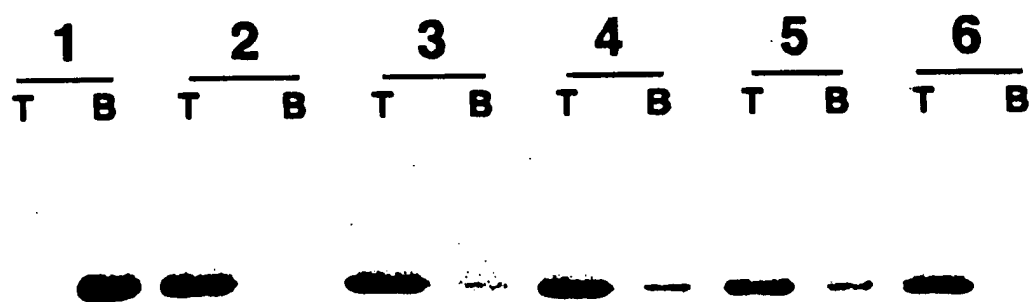


Fig. 2

4.4 S  
▼

11.3 S  
▼

19 S  
▼

P

Fig. 3A

Fig. 3B

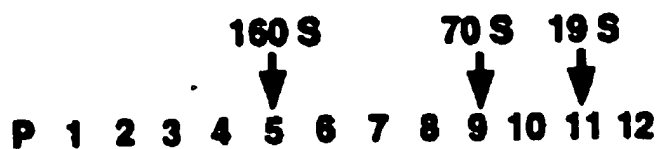


Fig. 4A



Fig. 4B



Fig. 4C



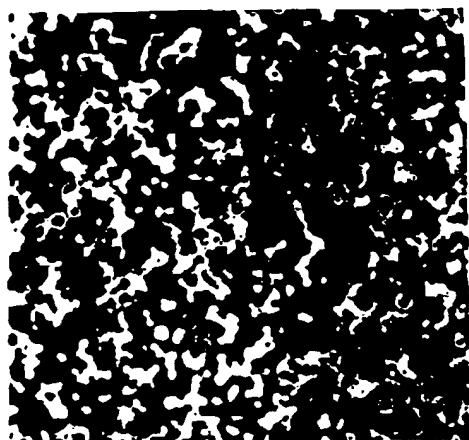


Fig. 5A

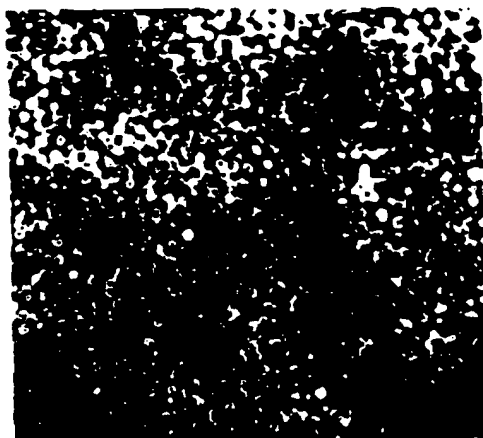


Fig. 5C

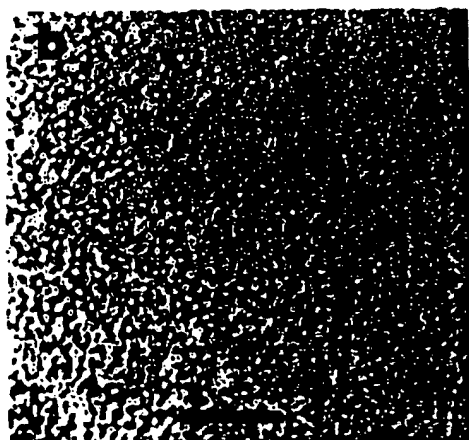


Fig. 5B

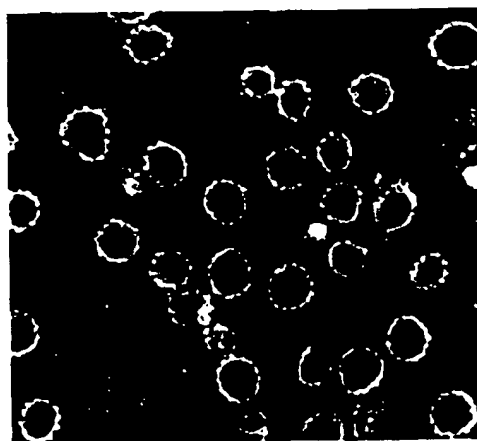


Fig. 5D

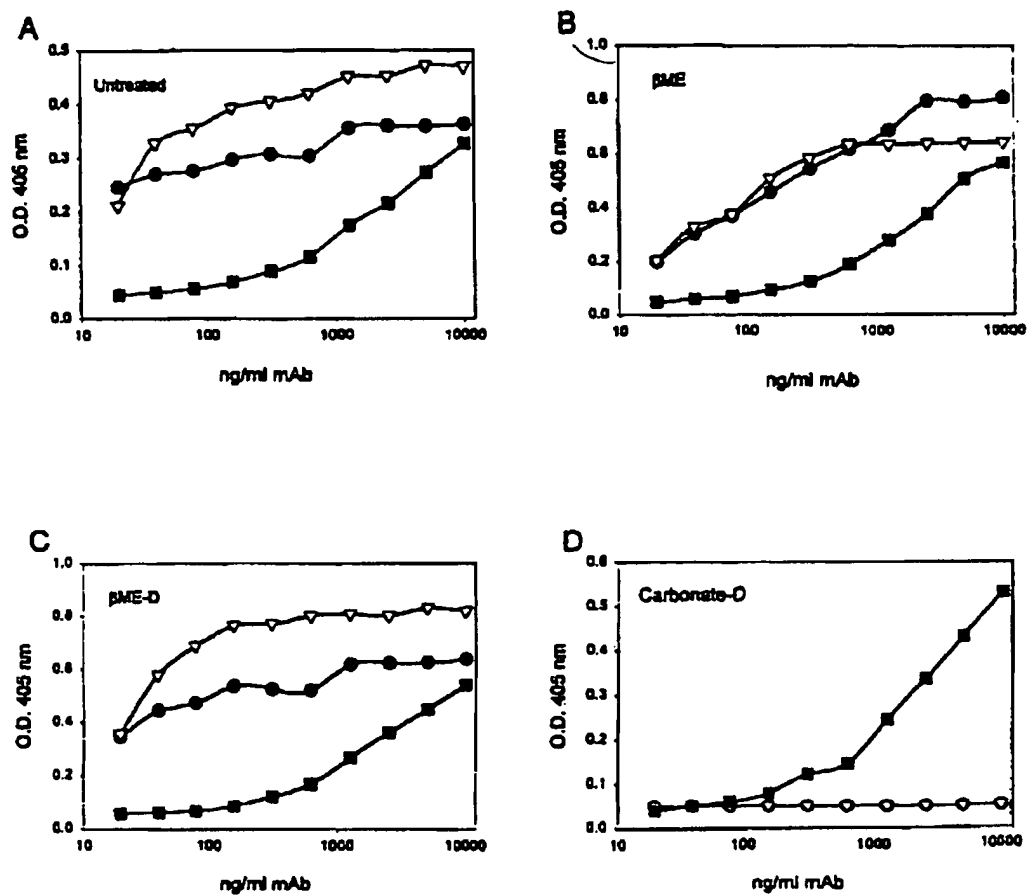


FIGURE 6

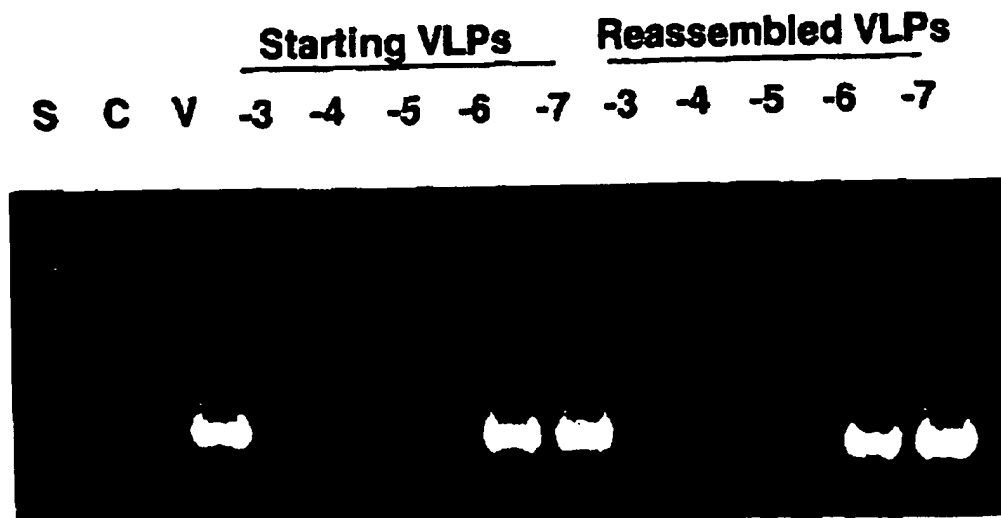
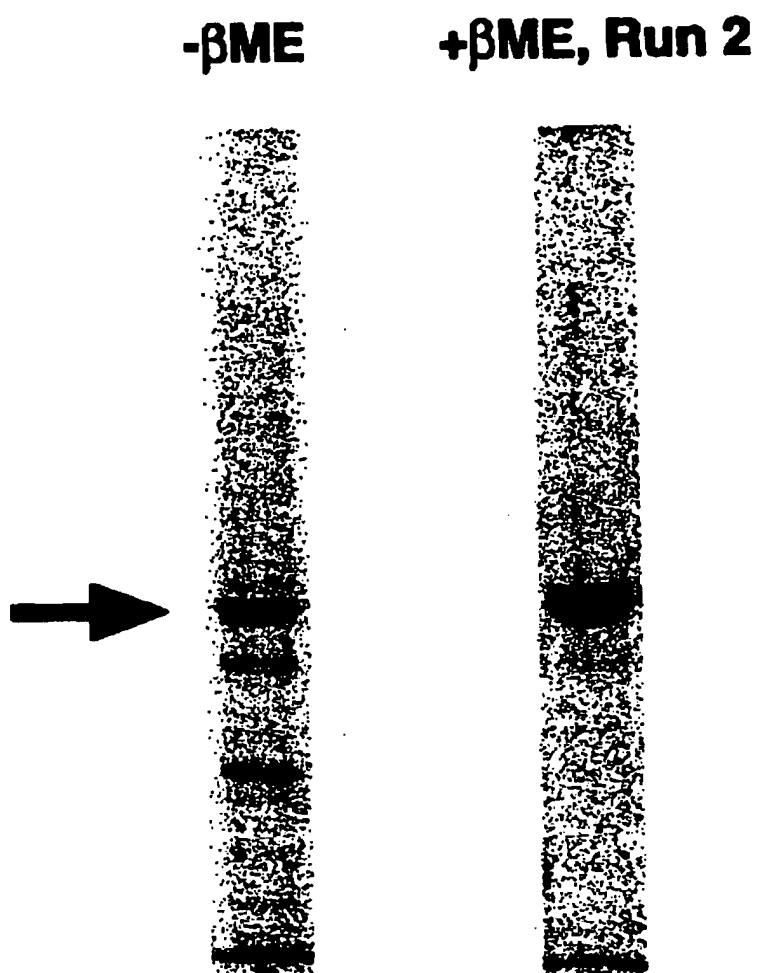


Fig. 7A



Fig. 7B



**Fig. 8**



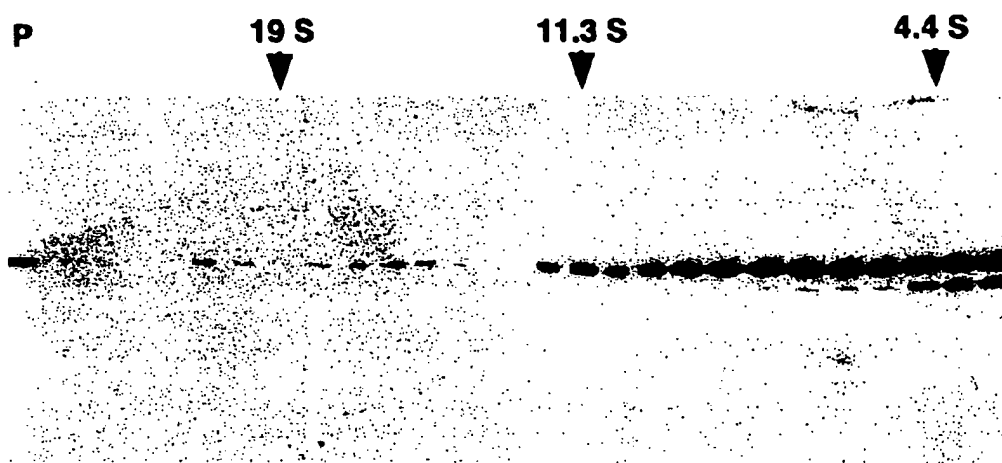
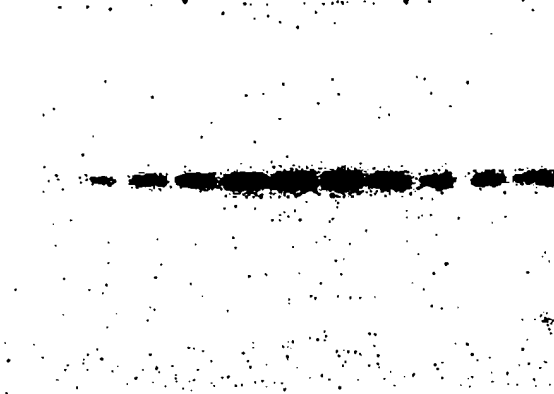


Fig. 9

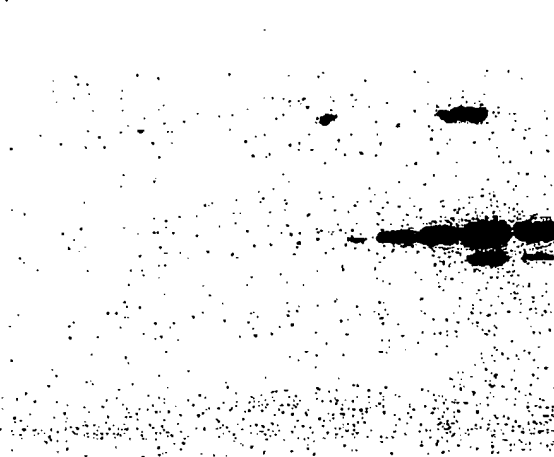
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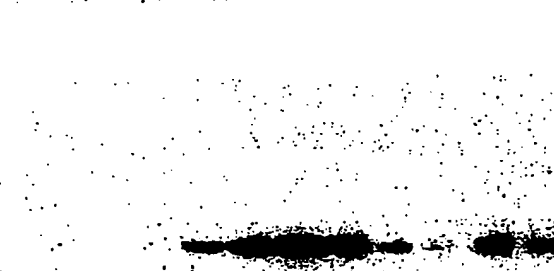
**Fig. 10A**



**Fig. 10B**



**Fig. 10C**



1

**IN VITRO METHOD FOR  
DISASSEMBLY/REASSEMBLY OF  
PAPILLOMAVIRUS VIRUS-LIKE PARTICLES  
(VLPs). HOMOGENEOUS VLP AND  
CAVSOMERE COMPOSITIONS PRODUCED  
BY SAID METHODS: USE THEREOF AS  
VEHICLE FOR IMPROVED PURIFICATION,  
AND DELIVERY OF ACTIVE AGENTS**

**CROSS REFERENCE TO RELATED  
APPLICATIONS**

This application is a continuation-in-part of application Ser. No. 10/138,739, filed May 6, 2002 now abandoned, and is a continuation-in-part of application Ser. No. 09/457,594, filed Dec. 9, 1999 now U.S. Pat. No. 6,962,777, and application Ser. No. 09/457,594 is a continuation-in-part of application Ser. No. 09/379,615, filed Aug. 24, 1999, now U.S. Pat. No. 6,416,945, which is a divisional of application Ser. No. 08/923,997, filed Sep. 5, 1997, now abandoned, and application Ser. No. 10/138,739 is a continuation of application Ser. No. 09/379,615, filed Aug. 24, 1999, now U.S. Pat. No. 6,416,915, which is a divisional of application Ser. No. 08/923,997, filed Sep. 5, 1997, now abandoned, the contents of which are incorporated herein by reference in their entireties.

**FIELD OF THE INVENTION**

The present invention provides a highly efficient means of disassembly of papillomavirus virus-like particles (VLPs) into capsomeres and/or smaller subunits, and reassembly into VLPs. These reassembled VLP-containing compositions produced by the invention express conformational, neutralizing epitopes and have high homogeneity and therefore comprise effective diagnostic and prophylactic agents for diagnosis or prevention of papillomavirus infection. Also, the present invention relates to the use of such VLPs for encapsulation of desired moieties, e.g., diagnostic or therapeutic agents, and the use thereof as "pseudovirions" for evaluating the efficacy of putative vaccines or therapeutics.

**BACKGROUND OF THE INVENTION**

Papillomaviruses infect a wide variety of different species of animals including humans. Infection is typically characterized by the induction of benign epithelial and fibroepithelial tumors, or warts at the site of infection. Each species of vertebrate is infected by a species-specific set of papillomavirus, itself comprising several different papillomavirus types. For example, more than sixty different human papillomavirus (HPV) genotypes have been isolated. Papillomaviruses are highly species-specific infective agents. For example, canine and rabbit papillomaviruses cannot induce papillomas in heterologous species such as humans. Neutralizing immunity to infection against one papillomavirus type generally does not confer immunity against another type, even when the types infect a homologous species.

In humans, papillomaviruses cause genital warts, a prevalent sexually-transmitted disease. HPV types 6 and 11 are most commonly associated with benign genital warts condylomata acuminata. Genital warts are very common, and subclinical or inapparent HPV infection is even more common than clinical infection. While most HPV-induced lesions are benign, lesions arising from certain papilloma-

2

virus types, e.g., HPV-16 and HPV-18, can undergo malignant progression. Moreover, infection by one of the malignancy-associated papillomavirus types is considered to be a significant risk factor in the development of cervical cancer, the second most common cancer in women worldwide. Of the HPV genotypes involved in cervical cancer, HPV-16 is the most common, being found in about 50% of cervical cancers.

In view of the significant health risks posed by papillomavirus infection generally, and human papillomavirus infection in particular, various groups have reported the development of recombinant papillomavirus antigens and their use as diagnostic agents and as prophylactic vaccines. In general, such research has been focused toward producing prophylactic vaccines containing the major capsid protein (L1) alone or in combination with the minor capsid protein (L2). For example, Ghim et al, *Virology*, 190:548-552 (1992), reported the expression of HPV-1 L1 protein, using vaccinia expression in Cos cells, which displayed conformational epitopes and the use thereof as a vaccine or for serological typing or detection. This work is also the basis of a patent application, U.S. Ser. No. 07/903,109, filed Jun. 25, 1992 (abandoned in favor of U.S. Ser. No. 08/216,506, filed on Mar. 22, 1994), which has been licensed by the assignee of this application. Also, Suzich et al, *Proc. Natl. Acad. Sci., U.S.A.*, 92:11553-11557 (1995), report that the immunization of canines with a recombinant canine oral papillomavirus (COPV) expressed in a baculovirus/insect cell system completely prevented the development of viral mucosal papillomas. These results are important given the significant similarities between many HPVs and COPV. For example, COPV, similar to HPVs associated with anogenital and genital cancer, infects and induces lesions at a mucosal site. Also, the L1 sequences of COPV shares structural similarities to HPV L1 sequences. Given these similarities, the COPV/beagle model is useful for investigation of L1 protein-containing vaccines, e.g., investigation of the protective immune response, protection from natural infection and optimization of vaccination protocols. (Id.)

Also, a research group from the University of Rochester reported the production of human papillomavirus major capsid protein (L1) and virus-like particles using a baculovirus/insect cell expression system (Rose et al, University of Rochester, WO 94/20137, published on Sep. 15, 1994). In particular, they reported the expression of the L1 major capsid protein of HPV-6 and HPV-11 and the production of HPV-6, HPV-11, HPV-16 and HPV-18 virus-like particles.

Further, a University of Queensland research group also purportedly disclosed the recombinant manufacture of papillomavirus L1 and/or L2 proteins and virus-like particles as well as their potential use as vaccines (Frazer et al, WO 93/02189, published Feb. 4, 1993).

Still further, a United States government research group reported recombinant papillomavirus capsid proteins purportedly capable of self-assembly into capsomere structures and viral capsids that comprise conformational antigenic epitopes (U.S. Pat. No. 5,437,951, Lowy et al, issued Aug. 1, 1995). The claims of this patent are directed to a specific HPV-16 DNA sequence which encodes an L1 protein capable of self assembly and use thereof to express recombinant HPV-16 capsids containing said HPV-16 L1 protein.

With respect to HPV capsid protein containing vaccines, it is widely accepted by those skilled in the art that a necessary prerequisite of an efficacious HPV L1 major capsid protein-based vaccine is that the L1 protein present conformational epitopes expressed by native human papillomavirus major capsid proteins (see, e.g., Hines et al,

*Gynecologic Oncology*, 53:13-20 (1994); Suzich et al, *Proc. Natl. Acad. Sci., U.S.A.*, 92:11553-11557 (1995)).

Both non-particle and particle recombinant HPV L1 proteins that present native conformational HPV L1 epitopes have been reported in the literature. It is known that L1 is stable in several oligomeric configurations, e.g., (i) capsomeres which comprise pentamers of the L1 protein and (ii) capsids which are constituted of seventy-two capsomeres in a T=7 icosahedron structure. Also, it is known that the L1 protein, when expressed in eukaryotic cells by itself or in combination with L2, is capable of efficient self-assembly into capsid-like structures generally referred to as virus-like particles (VLPs).

VLPs have been reported to be morphologically and antigenically similar to authentic virions. Moreover, immunization with VLPs has been reported to elicit the production of virus-neutralizing antibodies. More specifically, results with a variety of animal papillomaviruses (canine oral papillomavirus and bovine papillomavirus-4) have suggested that immunization with VLPs results in protection against subsequent papillomavirus infection. Consequently, VLPs composed of HPV L1 proteins have been proposed as vaccines for preventing diseases associated with human papillomavirus infections.

For example, it has been reported that the L1 protein can assemble into VLPs when expressed using recombinant baculovirus and vaccinia virus vectors and in recombinant yeast (Hagensee et al, *J. Virol.*, 68:4503-4505 (1994); Hoffmann et al, *Virology*, 209:506-518 (1995); Kimbaurer et al, *Proc. Natl. Acad. Sci. USA*, 89:12180-12184 (1992); Kimbaurer et al, *J. Virol.*, 67:6929-6936 (1993); Rose et al, *J. Virol.*, 67:1936-1944 (1993); Sasagawa et al, *Virology*, 206:126-135 (1995); Suzich et al, *Proc. Natl. Acad. Sci. USA*, 92:11553-11557 (1995); Volpers et al, *Virology*, 200:504-512 (1994); Zhou et al, *J. Virol.*, 68:619-625 (1994)).

Most previous recombinant L1 preparations isolated from eukaryotic cells have resulted in a variable population of VLPs approaching 55 nm in diameter, which are similar in appearance to intact virions. However, VLP assembly is somewhat sensitive to cell type. For example, L1 expressed in *Escherichia coli* is expressed largely in the form of capsomeres or smaller, with few or no capsids apparent either in the cell or upon purification (Rose et al, *J. Virol.*, 67:1936-1944 (1993); Li et al, *J. Virol.*, 71:2988-2995 (1997)). Similar results are observed when the polyoma virus VP1 protein is expressed in *E. coli* (Salunke et al, *Biophys. J.*, 56:887-900 (1989)).

To date there has not been reported an effective in vitro method for the quantitative disassembly and subsequent reassembly of papillomavirus VLPs. Such a method would be highly advantageous as it would potentially enable the preparation of more stable and/or homogeneous papillomavirus VLPs. This would be beneficial as homogeneity and stability are both significant concerns in vaccine preparation and characterization during manufacture. Furthermore, the ability to disassemble and reassemble VLPs has important applications to VLP purification. HPV L1 proteins expressed in eukaryotic cells spontaneously assemble to form VLPs, as discussed above. However, most protein purification procedures have been designed to purify proteins much smaller than the ~20 million dalton, 55 nm VLP. The potential to disassemble VLPs extracted from eukaryotic cells to the level of L1 capsomeres or smaller, purify the smaller components by conventional techniques, and then reassemble to form VLPs at the desired stage of the purification process is very powerful, and is currently being utilized in the purification of HPV-16<sub>n</sub> VLPs, as discussed

below (composed of a mutated form of the HPV-16 L1 protein from which the C-terminal 34 amino acids have been deleted). Finally the ability to disassemble and reassemble VLPs in vitro allows for the packaging of desired exogenous compounds within the reassembled VLP.

Earlier attempts at papilloma VLP disassembly have included experiments based on earlier work performed on polyomavirus, a related papovavirus, wherein it was shown that both the reduction of disulfides and chelation of cations were essential for virion disassembly (Brady et al, *J. Virol.*, 23:717-724 (1977)). However, in the case of HPV VLPs it has been shown that the low levels of reducing agent (1-10 mM DTT) which provide for optimal polyomavirus disassembly in the presence of low levels of chelating agents (e.g., 0.5-10 mM EGTA) were only slightly effective at disassembly of papillomavirus VLPs (see Table 1, Li et al, *J. Virol.*, 71:2988-2995 (1997)). By contrast, partially trypsinized HPV-11 L1 VLPs have been reported to disassociate effectively under such conditions (Li et al, *J. Virol.*, 71:2988-2995 (1997)). However, this is disadvantageous as the use of protease may result in adverse effects, e.g., removal of neutralizing epitopes.

Also, Sapp and coworker demonstrated that "partial disassembly" of HPV-33 VLPs could be achieved by treatment with reducing agent alone (20 mM DTT). However, the extent of VLP breakdown was not determined (Sapp et al, *J. Gen. Virol.*, 76:2407-2412 (1995)).

As discussed above, HPV capsid assembly requires correctly-folded L1 protein. However, additional factors significant for VLP formulation and stability have not been well elucidated. With respect thereto, it is generally known that VLP assembly can be affected by numerous factors. For example, factors and conditions known to affect assembly for other viruses include, by way of example: pH, ionic strength, posttranslational modifications of viral capsid proteins, disulfide bonds, and divalent cation bonding, among others. For example, the importance of cation bonding, specifically calcium, in maintaining virion integrity has been shown for polyomavirus (Brady et al, *J. Virol.*, 23:717-724 (1977)), and rotavirus (Gajardo et al, *J. Virol.*, 71:2211-2216 (1997)). Also, disulfide bonds appear to be significant for stabilizing polyomavirus (Walter et al, *Cold Spring Harb Symp. Quant. Biol.*, 39:255-257 (1975); Brady et al, *J. Virol.*, 23:717-724 (1977)); and SV40 viruses (Christensen et al, *J. Virol.*, 21:1079-1084 (1977)). Also, it is known that factors such as pH and ionic strength influence polyomavirus capsid stability, presumably by affecting electrostatic interactions (Brady et al, *J. Virol.*, 23:717-724 (1977); Salunke et al, *Cell*, 46:895-904 (1986); Salunke et al, *Biophys. J.*, 56:887-900 (1980)). Also, it is known that post-translational modifications of some viral capsid proteins may affect capsid stability and assembly, e.g., glycosylation, phosphorylation, and acetylation (Garcea et al, *Proc. Natl. Acad. Sci. USA*, 80:3613-3617 (1983); Xi et al, *J. Gen. Virol.*, 72:2981-2988 (1991)). Thus, there are numerous interrelated factors which may affect capsid stability, assembly and disassembly which vary widely even for related viruses.

Therefore, there exists a need in the art for elucidation of the factors that affect papillomavirus VLP assembly and disassembly. Moreover, based thereon, there exists a need in the art for an efficient in vitro method of disassembly and reassembly of papillomavirus VLPs which results in VLPs having good homogeneity, stability, and immunogenic properties, i.e., those which present conformational and more particularly neutralizing epitopes expressed on the surface of native, intact papillomavirus virions. Moreover, there is a significant need for methods for disassembly and reassembly

of papillomavirus VLPs which obviate the problems of partial VLP disassembly and which avoid the use of protease used in prior methods of generating papillomavirus capsomeres.

#### OBJECTS OF THE INVENTION

Thus, it is an object of the invention to solve the problems of the prior art.

More specifically, it is an object of the invention to provide a novel method for disassembly and reassembly of papillomavirus VLPs.

Still more specifically, it is an object of the invention to provide a novel method for disassembly and reassembly of human papillomavirus VLPs.

It is also an object of the invention to provide a method which enables quantitative disassembly and assembly of papillomavirus VLPs in large quantities.

It is another object of the invention to provide papillomavirus VLP-containing compositions, preferably human papillomavirus VLP-containing compositions, of improved quality, e.g., improved homogeneity, immunogenicity, and/or stability.

It is another object of the invention to provide an improved means of VLP purification by incorporating VLP disassembly/reassembly within the purification process.

It is still another object of the invention to provide a method for encapsulating desired moieties in papillomavirus VLPs, e.g., therapeutic or diagnostic agents.

It is another object of the invention to provide papillomavirus VLPs, preferably human papillomavirus VLPs, which contain desired therapeutic or diagnostic agents contained therein, e.g., anti-cancer agents or antiviral agents.

It is still another object of the invention to generate "pseudovirions" for HPV virus types wherein recoverable quantities of HPV virions are not currently available by the encapsulation of exogenous compounds into HPV VLPs constructed using L1 and L1/L2 proteins of said HPV papillomavirus, in particular a DNA corresponding to the genome of said HPV or a fragment or mutated form thereof, or a DNA encoding a selectable marker such as B-galactosidase.

It is still another object of the invention to provide a novel method of delivery of a desired moiety, e.g., a DNA to desired cells wherein the delivery vehicle for such moiety, e.g., sense or antisense DNA, comprises a papillomavirus VLP.

It is still another object of the present invention to use pseudovirions based on HPV VLPs in an in vitro assay for assaying the efficacy of potential HPV vaccines which assays the ability of neutralizing antibodies to inhibit the insertion of DNA encapsulated therein into cells.

#### BRIEF DESCRIPTION OF THE INVENTION

Therefore, the invention generally relates to a novel method for disassembly and reassembly of papillomavirus VLPs, preferably human papillomavirus VLPs in vitro.

As discussed above, papillomavirus VLPs are constituted primarily of a structural protein L1, which is stable as pentameric capsomeres or capsids composed of 72 capsomeres. Such VLPs may also comprise the L2 protein. In particular, by the judicious choice of experimental conditions, the present inventors have surprisingly discovered that quantitative disassembly of papillomavirus VLPs (almost entirely to the level of capsomeres or smaller), and subsequent reassembly can be consistently achieved by prolonged

exposure of VLPs, to a solution comprising a high concentration of at least one sulfhydryl reducing agent preferably contained in appropriate ionic strength buffers. In one embodiment, the ionic strength may be from about 0.1M to 1.5M, preferably from about 0.1M to 1.0M. In another embodiment, the ionic strength may be up to, but does not exceed, 0.5M. Specifically, the subject method results in reassembled VLP-containing compositions of very high homogeneity, predominantly comprising particles in the range of full-size VLPs, averaging  $56.5 \pm 7.0$  nm ( $n=15$ ) with very few partially assembled VLPs or smaller complexes. The yields are also very high, i.e., quantitative, averaging 80-90% in terms of total L1 protein from starting material to reassembled VLPs under optimal disassembly conditions. Moreover, essentially all the previously disassociated capsomeres reassemble to produce soluble, filterable, full-size VLPs.

It has been unexpectedly found that use of such conditions results in papillomavirus VLP compositions of enhanced homogeneity (relative to VLP starting material and to available VLP compositions), i.e., homogeneous compositions constituted almost entirely of papillomavirus VLPs which are 55 nm, 150 S. Further, it has been shown that these homogeneous VLPs present conformational, neutralizing HPV epitopes, a prerequisite of an effective prophylactic HPV VLP-based vaccine. Also, it has been surprisingly found by the inventors that chelators do not enhance VLP disassembly, and moreover may inhibit reassembly of capsomeres into VLPs. As discussed in greater detail infra, these findings were surprising because for a related papovavirus, polyomavirus, it has been shown that both exposure to low levels of sulfhydryl reducing agent and chelation of calcium ions were essential for virion disassembly. By contrast, such conditions are only slightly effective for disassembly of papilloma VLPs.

As noted, it has also been found that the papillomavirus capsomere and VLP compositions, produced according to the invention present structure-specific (conformational), in particular neutralizing epitopes found on the surface of intact papillomavirus virions. This has been demonstrated both by their reactivity with neutralizing and structure-specific anti-L1 papillomavirus monoclonal antibodies in an ELISA assay and by their ability to induce the synthesis of antibodies which neutralize papillomavirus virus infection in an RT-PCR infection assay. Therefore, they are well suited for use as prophylactic agents for preventing PV infection and for diagnostic purposes. Furthermore, the subject methods for VLP disassembly and reassembly can be applied at different degrees of VLP purity. This allows for disassembly of crude mixtures of VLPs, purification of the smaller, soluble VLP components (which is simpler due to their greatly diminished size), followed by reassembly at the desired stage of the purification process. Also, this step allows for the removal of other intact adventitious viruses.

Also, as discussed in greater detail infra, the subject methods further provide for the introduction of desired moieties, e.g., DNAs, proteins, peptides, hormones, radio-nuclides, anti-cancer agents and antiviral agents into VLPs during reassembly. This is advantageous as such VLPs may be used as delivery vehicles (for insertion of desired moieties into cells) and as "pseudovirions" for evaluating the prophylactic efficacy of papillomavirus vaccines.

The present inventors hypothesize that papillomavirus VLP disassembly requires prolonged exposure to very high levels of reducing agent because of the presence of stabilizing disulfide bonds which likely are buried and inaccessible, and that exposure of these bonds to solvent by local

structural fluctuations is very infrequent. (This phenomenon is discussed in greater detail in application Ser. No. 08/888, 050, filed on Jul. 3, 1997.) Apparently, upon prolonged exposure at high reducing agent concentrations and at appropriate ionic strength, e.g., in one embodiment not to exceed 0.5M, and in another embodiment, from about 0.1M to about 1.5M, these bonds become accessible over time.

## DEFINITIONS

### Major Capsid Protein or L1 Protein

This refers to the structural protein of papillomavirus (PV) which constitutes the major portion of the PV capsid structure. This protein has reported application in the preparation of HPV vaccines and as a diagnostic agent.

### Minor Capsid Protein or L2 Protein

This refers to the structural protein of papillomavirus which constitutes a minor portion of the PV viral capsid structure.

### Virus-like Particles or VLPs

This refers to the capsid-like structures which result upon expression and assembly of a papillomavirus L1 DNA sequence alone or in combination with an L2 DNA sequence. VLPs are morphologically and antigenically similar to authentic virions. VLPs may be produced in vivo, in suitable host cells, e.g., mammalian and insect host cells, or may form spontaneously upon purification of recombinant L1 proteins. Additionally, they may be produced using L1 fragments or mutated forms thereof e.g. L1 proteins that have been modified by the addition, substitution or deletion of one or more amino acids. L1 mutants that fall within the scope of the present invention are those that upon VLP reassembly present at least one native PV conformational epitope. For example, this includes L1 proteins which have been truncated at the ultimate conserved glutamine residue at the carboxy-terminus. Cleavage at said glutamine residue will remove, on average, 30 to 40 amino acid residues of the L1 protein. Suitable mutants or fragments can be determined based on the reactivity of said L1 proteins with neutralizing antiserum or their ability to elicit neutralizing antiserum.

### Pseudovirion

This refers to VLPs, containing exogenous marker compounds, composed of L1 or L1 and L2 proteins or fragments or mutated forms thereof of a specific PV type. Pseudovirions can be used to test the efficacy of substances, such as antibodies, to block specific viral binding and/or uptake into target cells in cases where authentic virus is not available.

### Correctly-folded L1 Protein

This refers to L1 protein, fragment thereof or mutated form thereof, (either monomeric, in the form of small oligomers (dimers-tetramers) or capsomeres), which is in a conformation suitable for reassembly into VLPs and which retains epitopes present on native viral capsids or VLPs.

### Capsomeres

This refers to an oligomeric configuration of the L1 protein which is constituted of L1 pentamers.

### Capsids

This refers to the structural portion of the papillomavirus which is comprised of capsomeres. More specifically, it is constituted of seventy-two capsomeres in a T=7 icosahedron structure.

### Conformational L1 HPV Epitope

This refers to an epitope expressed on the surface of correctly-folded L1 protein which is also expressed by an L1 protein or fragment, or mutated form thereof which is also

expressed by an L1 protein of a corresponding wild-type, infectious HPV. It is well accepted by those skilled in the art that the presentation of conformational epitopes is essential to the efficacy (both as prophylactic and diagnostic agents) of HPV L1 protein immunogens.

### Conformational Neutralizing L1 HPV Epitope

This refers to an epitope expressed on the surface of correctly-folded L1 protein, fragment or mutated form thereof, which is also expressed by an L1 protein of a corresponding wild-type, infectious HPV, and which elicits neutralizing antibodies. It is well accepted by those skilled in the art that the presentation of conformational neutralizing epitopes is essential to the efficacy (both as prophylactic and diagnostic agents) of HPV L1 protein immunogens.

### Conformational Antibody

This refers to an antibody that specifically binds an epitope expressed on a correctly-folded L1 protein but not on denatured L1 protein.

### Reducing Agent Solution of High Concentration

This refers to a solution containing an amount of at least one sulphhydryl reducing agent, e.g., glutathione, 13-mercaptoethanol, dithiotreitol, cysteine, hydrogen sulfide, or 2-mercaptoethanesulfonic sodium or potassium salt which provides for at least 70% disassembly of papillomavirus VLPs, when VLPs are contacted therewith for prolonged periods, typically at least 2 hours, and more preferably at least 16 hours. The concentration of the reducing agent may vary dependent upon the particular reducing agent. In the case of B-mercaptoethanol, this amount will preferably be at least 1% by weight, more preferably at least 3-5% by weight. In the case of dithiotreitol, the amount will preferably be at least about 100 mM.

### Prolonged Exposure or Contacting of VLPs with Reducing Agent Solution of High Concentration

This refers to the time that VLPs are contacted with reducing agent solution of high concentration that is sufficient to provide for at least 70% disassembly of VLPs into capsomeres. Preferably, such prolonged exposure will result in 70-90% disassembly and optimally virtually total VLP disassembly. This time will vary for different PV types, and may also depend upon the cells that VLPs are expressed (starting material), degree of purity (presence or absence of aggregates), pH, and ionic strength. Additionally, VLPs formed from mutated or chemically-altered L1 protein, e.g., C-terminally truncated L1 protein, may disassemble under milder conditions. Generally, this exposure will be for at least 2 hours (in the case of HPV-16<sub>T</sub> VLPs), and more typically longer, i.e., at least 12 hours, more preferably at least 16 hours (in the case of HPV-11 VLPs).

## DETAILED DESCRIPTION OF FIGURES

FIG. 1: SDS/PAGE analysis of purified HPV-11 L1 protein. The protein was mixed with sample preparation buffer in the absence (lane 1) or presence (lane 2) of 2 mM DTT and boiled for 2 minutes prior to gel electrophoresis. Shown on the left are the positions at which molecular weight standards (in  $\text{Dax}10^{-3}$ ) migrated.

FIG. 2: 30% sucrose cushion analysis of HPV-11 VLP disassembly. HPV-11 preparations were treated at 4° C. as described in the text, and samples were taken at the top (T) or bottom (B) of the sucrose cushion prior to gel electrophoresis. Group 1, untreated, purified HPV-11 VLP starting material in PBS. Group 2, VLPs incubated with 5% BME for 16 hours. Group 3, VLPs incubated with 5% B-ME for 1

hour. Group 4, VLPs incubated with 2% BME for 16 hours. Group 5, VLPs incubated with 0.5% B-ME for 16 hours. Group 6, VLPs incubated with 10 mM DTT, 5 mM EDTA for 16 hours.

FIG. 3: 5-20% linear sucrose gradient analysis of disassembled HPV-11 VLPs. VLPs in PBS were incubated with 5% B-ME (a), or 200 mM NaHCO<sub>3</sub>, pH 9.6 (b) for 16 hours at 4° C. and then centrifuged on a 5-20% linear sucrose gradient as described in the text. The gradient was collected in 25 fractions (0.5 ml), and the pellet (P) was resuspended in 0.5 ml PBS. Shown is an immunoblot demonstrating the position of the L1 protein across the gradient. Also indicated are the peak positions at which sedimentation standards migrated when run on separate gradients.

FIG. 4: 10-65% linear sucrose gradient analysis of HPV-11 VLPs in various states of assembly. An aliquot of purified VLP starting material (a) was incubated with 5% B-ME for 16 hours at 4° C. (b). A portion of B-ME-treated VLPs were then reassembled by dialysis into PBS-0.5 NaCl to remove reducing agent (c). The samples are then centrifuged on 10-65% linear sucrose gradients as described in the text. Each gradient was collected in 12 fractions (1 ml), and the pellet (P) was resuspended in 1 ml PBS. Shown are immunoblots demonstrating the positions at which the L1 protein migrated on the different gradients. Also indicated are the peak positions at which sedimentation standards migrated, as in FIG. 3.

FIG. 5: Electron micrographs of HPV-11 VLPs in various states of assembly. VLPs, treated as described, were stained with 2% phosphotungstic acid, applied to grids, and photographed at magnifications of 15-25,000 times. a, purified VLP starting material, b, VLPs disassembled to the level of capsomeres by incubation with 5% B-ME for 16 hours at 4° C. c, VLPs reassembled from disassembled VLPs by dialysis into PBS-0.5 NaCl, d, the central region of image c at greater magnification. Scale bar: a,c=200 nm; b,d=100 nm.

FIG. 6: Reaction of intact and disassembled VLPs with HPV-11 structure-specific monoclonal antibodies. HPV-11 L1 VLP starting material (A), VLPs disassembled by treatment with 5% B-ME either without (B) or with (C) subsequent dialysis into PBS-0.5 M NaCl to remove reducing agent, and VLPs disassembled in the presence of 200 mM carbonate, pH 9.6 and then dialyzed into PBS-0.5 M NaCl (D) were attached to the wells of microtiter plates. HPV-11 structure-specific monoclonal antibodies H-11 F1 (HPV-11 neutralizing;) and H11.A3 (HPV-11 non-neutralizing;) were tested for immunoreactivity to the bound antigens in an ELISA as described in the Materials and Methods. Reactivity with monoclonal antibody AU1 (■), which recognizes a linear epitope found on HPV-11 L1, was used as a control to demonstrate antigen attachment to the microtiter wells.

FIG. 7: Comparison of the ability of antisera raised against initial purified HPV11 VLPs, and reassembled VLPs, to neutralize HPV-11 virus. Anti-HPV-11 sera were incubated with HPV-11 virions for 60 min at 37° C. before addition to HaCaT cells. Alternatively, virions were added to cells without pre-incubation with serum. Six days post-infection, the cells were harvested and total RNA was extracted. Ten percent of the total RNA was used for reverse transcription, and ten percent of the resulting cDNA was then used as template for nested PCR using primers specific for the HPV-11 E1'E4 spliced message. PCR products were separated on 2% agarose gels. Gels were stained with ethidium bromide and examined under UV light for the presence of the ~0.6 kb E1'E4 band (a). PCR amplification of B-actin was performed on all cDNA samples as an internal control (b). The expected size of the B-actin band is

~0.6 kb. Lane S contains molecular size markers. Lane C represents reactions carried out with RNA from cells incubated without virus and Lane V represents cells incubated with virus that had not been pre-incubated with serum. As expected, the E1'E4 band is detected in virus-infected but not in uninfected cells. The next lanes contain PCR products from cells infected with virus that had been pre-incubated with serial log<sub>10</sub> dilutions of anti-HPV-11 antiserum (10<sup>-3</sup>-10<sup>-7</sup>) raised against initial purified HPV-11 VLPs and reassembled VLPs as indicated.

FIG. 8: SDS/Page comparison of HPV16<sub>77</sub> VLPs in the assembled (-BME) and disassembled (+BME, Run 2) states, indicating the greater purity of VLPs purified in the disassembled state. The position at which HPV-16<sub>77</sub> L1 protein migrates is indicated by the arrow.

FIG. 9: 5-20% linear sucrose gradient analysis of disassembled HPV-16<sub>77</sub> VLP's. Final purified +BME Run 2 VLPs (see Table 3) in PBS were incubated with 4% βME for 16 hours at 4° C. and then centrifuged on a 5-20% linear sucrose gradient as described in the Methods section. The gradient was collected in 25 fractions (0.5 ml), and the pellet (P) was resuspended in 0.5 ml PBS. Shown is an immunoblot, probed with the HPV-16 specific monoclonal antibody 16-E, demonstrating the position of the L1 protein across the gradient. Also indicated are the peak positions at which sedimentation standards migrated when run on separate gradients.

FIG. 10: 10-65% linear sucrose gradient analysis of HPV-16<sub>77</sub> VLPs in various states of assembly. An aliquot of (a) purified VLP starting material (+βME Run 2; see Table 3) was incubated with 4% βME for 16 hours at 4° C. (b). A portion of B-ME-treated VLPs were then reassembled by dialysis into PBS-0.5 NaCl to remove reducing agent (c). The samples were then centrifuged on 10-65% linear sucrose gradients as described in the text. Each gradient was collected in 12 fractions (1 ml), and the pellet (P) was resuspended in 1 ml PBS. Shown are immunoblots, probed with the HPV-16 specific monoclonal antibody 16-E, demonstrating the positions at which the L1 protein migrated on the different gradients. Also indicated are the peak positions at which sedimentation standards migrated, as in FIG. 9.

#### DETAILED DESCRIPTION OF THE INVENTION

As discussed, the present invention generally relates to a novel method which provides for highly effective disassembly of papillomavirus VLPs, i.e., at least 70% disassembly, more preferably 70-90% disassembly, and most preferably total VLP disassembly, which comprises prolonged exposure of papillomavirus VLPs comprised of L1, L1 fragments, or a mutated L1 proteins or a combination of L1 proteins fragments or mutated forms thereof, and L2 proteins, fragments, or mutated forms thereof to a sulfhydryl reducing agent solution at high concentration. In general, the concentration of the reducing agent will be at least 1% by weight, and more preferably about 3-5% by weight. Preferably, the reducing agent-containing solution will have an ionic strength which is at most about 1.5M, and preferably lower, typically from about 0.1M to about 1.0M. In another embodiment, the reducing agent-containing solution has an ionic strength which does not exceed 0.5M.

However, reducing agent concentrations and ionic strength may vary for different papillomavirus types, the host cells they are obtained from, mutated and/or chemically-altered forms of the L1 protein, and purity. More specifically, the present inventors have elucidated conditions

for maximal disassembly of purified VLPs in vitro, which provides for efficient subsequent reassembly. It has been discovered that prolonged incubation of papillomavirus VLPs with relatively high concentrations of reducing agents at ionic strengths which are at most 1.5M, and more preferably around physiological ionic strength or higher, generates homogeneous soluble capsomeres from purified VLPs. Moreover, it has been found that upon removal or alternatively by oxidation of the reducing agent, a defined population of intact, appropriately-sized VLPs is obtained.

This has been shown in particular using HPV-11i VLPs produced in a baculovirus/insect cell system, i.e., in *Trichoplusia ni* (High Five®) cells infected with a recombinant baculovirus containing the entire HPV-11 L1 DNA sequence. However, based on these results, it is reasonable to conclude that similar results will be achieved using papillomavirus VLPs produced from other types and species, in particular other human papillomavirus types. This is reasonable as numerous papillomavirus L1 proteins have been demonstrated to result in VLPs when expressed in suitable recombinant expression vector systems. Also, such results may be achieved using L1 fragments, e.g. carboxy terminal-deletions, and mutated forms of L1.

Likewise, it is reasonable to expect that similar results will be achieved using papillomavirus VLPs comprised of a combination of L1 and L2 proteins, or fragments or mutated forms thereof, as VLPs comprised of L1 or L2 appear virtually identical to VLPs made only of L1 proteins. [However, assuming that L2 has a significant stabilizing role, the present inventors acknowledge that disassembly may require the use of higher concentrations of reducing agent, more prolonged exposure thereto, elevated pH and/or reduced ionic strength during disassembly.] Moreover, it is expected that the subject methods will be suitable for disassembly/assembly of VLPs obtained from any host cell system that results in the production of papillomavirus VLPs. While Applicants acknowledge that there exists some host cell differences, as discussed supra, many host cells have been reported to express papillomavirus VLPs in the form of VLPs.

In general, the desired VLP starting material will be produced in a suitable host cell system, e.g., a baculovirus/insect cell system, and extracted therefrom using known methods. The extraction technique will depend upon factors such as the specific host cells used, concentration, whether protein remains intracellular or is secreted, among other factors.

Disassembly of the VLPs can be performed at different levels of VLP purity. When performed in conjunction with purification, VLPs will be extracted from cells, disassembled, purified by conventional techniques, and reassembled at the desired degree of purity. In the cases where VLPs will be used to package exogenous compounds, or when disassembly/reassembly is performed to improve the homogeneity of the final product, the VLPs used will be of fairly high purity. In these instances, the VLPs used for disassembly will preferably be about 10-70% protein purity, more preferably about 10%-50% protein purity, and most preferably about 30-40% protein purity. Methods of determining VLP purity are known and include SDS-PAGE densitometric methods.

As discussed in detail, infra, in the materials and methods section, the present inventors developed a rapid screening assay for the study of VLP disassembly which uses a sucrose step-gradient. In this system, intact VLPs pellet through a 30% sucrose cushion, whereas non-aggregated capsomeres, smaller L1 oligomers or L1 monomers remain on top of the

cushion. Therefore, this assay method is beneficial as it facilitates the precise identification of conditions that result in maximal VLP disassembly.

In general, it was found that maximal VLP disassembly requires prolonged exposure of non-aggregated VLPs to a solution containing a high concentration of sulfhydryl reducing agent. As explained previously, prolonged exposure is the duration sufficient to result in at least 70% disassembly of VLPs, more preferably 70-90% VLP disassembly, and ideally virtually total VLP disassembly. In the case of recombinant HPV-11 L1 VLPs produced in the exemplified insect cell system, maximal disassembly occurred after about 16 hours at 4°C (using a solution containing 5% by weight of 13-mercaptoethanol). However, such exposure times may potentially be reduced using other VLP staffing materials, different pH conditions, higher reducing agent concentrations, and lower ionic strengths. For example, it has been found [results not shown] that substantial disassembly of VLPs formed by a C-terminally-truncated form of the HPV-16 L1 protein can be effected by exposure of such VLPs with a B-mercaptoethanol solution (4%) after about 2 hours at 4° C. As noted previously, preferred ionic strengths for disassembly will be at most 1.5M, more preferably at most 1.0M, and most preferably from about 0.1M to about 1.0 M. In another embodiment, the ionic strength will not exceed 0.5M.

The subject VLP disassembly method has been demonstrated to be effective using  $\beta$ -mercaptoethanol and dithiothreitol as the reducing agents. However, it is expected that other known reducing agents should provide similar results. Examples of suitable reducing agents useful in the invention include glutathione,  $\beta$ -mercaptoethanol, dithiothreitol, dithioerythritol, cysteine, hydrogen sulfide, 2-mercaptoethansulfonate salts, and mixtures thereof.

As noted, the present method contacts VLPs with a solution having a high sulfhydryl reducing agent concentration. Herein, this is defined to be a reducing agent concentration that results in substantial disassembly of VLPs, i.e., at least 70%, preferably at least 70-90%, and more preferably virtually total VLP disassembly, after prolonged exposure.

These high reducing agent concentrations will vary dependent upon the particular reducing agents or combination. In the case of B-mercaptoethanol, it has been found that a concentration of at least about 5% by weight (713 mM) results in optimal HPV-11 L1 VLP disassembly at physiological ionic strength. Lower concentrations of reducing agent and reduced exposure periods result in less effective VLP disassembly. For example, it has been found that 4% B-mercaptoethanol solutions also provide for effective disassembly (at least 70%).

It has also been found that the ionic strength is an important parameter in the disassembly method. Preferably, disassembly will be effected using a solution having an ionic strength which is at most 1.5M, i.e., around 0.1M to 1.0M. In one embodiment, the ionic strength does not exceed 0.5M. Suitable salts for obtaining solutions having such ionic strength include NaCl, KCl, and  $\text{NH}_4$  and more preferably will be effected at about "physiological" ionic strength (i.e., 0.15M NaCl) or lower. It has been found that higher ionic strengths render the VLP disassembly method less effective. In general, ionic strength will be at most about 1.5M, more preferably at most about 1.0M, and typically about 0.1M to 1.0M. In another embodiment, ionic strength will not exceed 0.5M.

It was also discovered that the presence of VLP aggregation has adverse effects on disassembly. This effect may be



avoided by removal of aggregated material, or potentially may be obviated by more prolonged exposure of the VLPs to the high concentration reducing agent solution. This likely occurs because the disulfide bonds are buried and thus inaccessible to reducing agent in aggregates, thereby preventing disassembly.

Also, as discussed, it has been surprisingly found that chelators, even at high concentrations, do not have a significant effect on HPV-11 VLP disassembly. This was shown using both EGTA and EDTA, both well known chelators, alone and in combination with dithiothreitol. As discussed previously, this is surprising because chelating agents have been reported to be necessary in VLP disassembly for a related papovavirus.

Furthermore, it has been found that carbonate buffer (0.2 M NaHCO<sub>3</sub>, pH 9.6) caused significant disassembly of HPV-11 VLPs. However, unlike disassembly induced by prolonged exposure to sulfhydryl reducing agents it was not possible to reassemble carbonate-treated VLPs. It is hypothesized that the carbonate treatment partially denatured the L1 protein. This demonstrates that only those methods (such as prolonged exposure to effective concentrations of sulfhydryl reducing agents) which disassemble VLPs while retaining correctly-folded L1 protein structure will produce material which is competent to reassemble into full-size, soluble, VLPs.

As noted, the subject disassembly of PV VLPs results in capsomeres of high homogeneity that present conformational, neutralizing epitopes as demonstrated by their reactivity with conformational and neutralizing monoclonal antibodies produced against the particular papillomavirus (HPV-11 exemplified). Moreover, under optimal conditions, the subject method results in a composition wherein VLPs appear to be totally broken down to capsomeres. Conversely, the subject disassembly of HPV-16<sub>7</sub> VLPs appears to result in a mixture of capsomeres, smaller L1 oligomers and L1 monomers. However, this mixture of L1 oligomers is also capable of quantitative reassembly. This indicates that the subject method yields correctly-folded L1 protein or fragments, or mutated forms thereof, in the form of capsomeres, smaller L1 oligomers, or L1 monomer, which are competent for VLP reassembly.

As discussed, a particular advantage of the invention is that said capsomeres, oligomers or monomers can then quantitatively assemble into VLPs simply by removal of the reducing agent solution. Removal of reducing agent may be accomplished by various methods, e.g., dialysis or column chromatography. Alternatively, addition of excess oxidants can potentially promote the reformation of the appropriate disulfide bonds, leading to VLP reassembly. As discussed above, reassembly is affected by the structural integrity of the correctly-folded L1 protein starting material. Also, the solubility of the starting material affects reassembly, as aggregated material will not reassemble quantitatively.

Reassembly is effected by removal of the sulfhydryl reducing agent or addition of oxidants and exposure of correctly-folded L1 protein starting material to equal higher ionic strength conditions, e.g., 0.15 to 1.5. Higher salt concentrations function to stabilize the VLPs. However, the addition of chelating agents has the opposite effect, i.e., it moderately inhibits reassembly.

Surprisingly, such reassembly results in VLPs which are much more homogenous in particle size than the original VLP starting material. This was demonstrated by comparison of the starting VLP material and reassembled VLP product on 10-65% linear sucrose gradients, and by examination under the electron microscope. Predominantly, par-

ticles in the range of full-size VLPs were detected, averaging 56.5±7.0 nm with very few partially assembled VLPs or smaller complexes apparent. Also, the yields are very high, averaging about 80-90% in terms of ratio of total L1 protein from starting material to reassembled VLPs using optimal reassembly conditions. Essentially, all of the disassembled starting material appear to reform soluble, filterable, full-size VLPs. Also, these VLPs exhibit conformational, neutralizing epitopes found on the surface of authentic papillomavirus virions and elicit neutralizing antibodies as potentially as the VLP starting material.

While these results are novel and unexpected, it is nevertheless expected, based on the teachings of the application, that one skilled in the art may achieve even greater VLP yields by varying protein concentration, pH, ionic strength and/or kinetics.

The present invention further provides methods for producing papillomavirus VLPs which have encapsulated therein a desired moiety or moieties. This will generally be accomplished by the following steps:

(i) obtaining VLPs of a desired papillomavirus, which are constituted of L1, or L1 fragments, or mutated forms of L1, or a combination of L1 and L2 proteins;

(ii) disassembling such VLPs by contacting such VLPs with a solution containing a high concentration of sulfhydryl-reducing agent having an appropriate ionic strength purification which is at most 1.5M, and, in another embodiment, does not exceed 0.5M;

(iii) contacting the disassembled VLPs with a solution containing a moiety to be encapsulated therein, and optionally also containing purified L2 protein (e.g., if the disassembled VLPs did not comprise L2 protein); and

(iv) reassembling said disassembled VLPs by removal of the sulfhydryl reducing agent or by addition of excess oxidant, at an appropriate ionic strength, typically 0.15 to 1.5 M, thereby producing VLPs containing the desired moiety(ies).

The disassembly and reassembly steps are conducted as described previously, i.e., disassembly is effected by use of high concentrations of sulfhydryl reducing agents, typically at least 1% by weight, or higher, and for prolonged periods, i.e., at least 2 hours, and typically longer, e.g., at least 16 hours. As discussed, the exposure time and concentration of reducing agent are affected by the type of papillomavirus VLPs, the host cell system in which they are produced, mutations within the L1 protein (e.g., C-terminal truncations), level of purity, whether aggregates are present, and potentially whether the VLPs are comprised of L1, L1 fragments, or mutated forms thereof, or a combination of L1 and L2. Reassembly occurs upon the removal or oxidation of the sulfhydryl reducing agent.

While it is reasonable to assume that VLPs comprised of L1 and L2 will disassemble under similar conditions as L1 based VLPs, the L2 protein may serve a stabilizing function. Therefore, disassembly of VLPs comprised of L1 and L2 may potentially require higher reducing agent concentrations, more prolonged exposure thereto, reduced ionic strength, elevated pH or a combination thereof. Alternatively, VLPs constituted entirely of PV L1 proteins may be disassembled as taught herein, and purified L2 protein (produced by recombinant methods) may be added during the reassembly step.

The moieties that may be encapsulated in the VLPs include therapeutic and diagnostic moieties, e.g., nucleic acid sequences, radionuclides, hormones, peptides, antiviral agents, antitumor agents, cell growth modulating agents, cell growth inhibitors, cytokines, antigens, toxins, etc.

The subject VLPs, which contain a desired moiety encapsulated therein, upon administration to a desired host, preferably human, should be taken up by cells normally infected by the particular papillomavirus, e.g., epithelial cells, keratinocytes, etc., thereby providing for the potential internalization of said encapsulated moiety into these cells. This may facilitate the use of the subject VLPs for therapy (as opposed to prophylactics) because it enables the delivery of a therapeutic agent into a desired cell site, e.g., a cervical cancer site. Given the fastidiousness of PVs in general, this may provide a highly selective means of delivering desired moieties to target cells. For example, it may provide a means of delivery of nucleic acid sequences, e.g., a DNA encoding a therapeutic polypeptide, or an antisense sequence.

The moiety or moieties encapsulated, of course, should not adversely affect VLP assembly and/or stability. This may be determined by producing VLPs containing the desired moiety and assessing its effects, if any, on VLP assembly and/or stability.

In the case of DNAs or RNAs, the encapsulated nucleic sequence can be up to 8 kilobases, the size of the PV genome. However, typically the encapsulated sequences will be smaller, e.g., on the order of 1-2 kilobases. Typically, these DNAs will encode a desired polypeptide, e.g., therapeutic polypeptide, such as an enzyme, hormone, growth factor, etc. This sequence will further be operably linked to sequences that facilitate the expression thereof in the targeted host cells.

Another application of VLPs containing encapsulated DNAs are as "pseudovirions". In this regard, numerous papillomaviruses, including those involved in human diseases, are rare, can not be propagated readily in vitro and cannot be easily purified from human cell sources in amounts that facilitate the use thereof in antibody neutralization assays. This is problematic, as it prevents or makes difficult evaluating the feasibility of vaccines or therapeutics for protection against these specific HPV viruses. Examples of HPV types for which no stocks are currently available include HPV 33 and 35.

The present invention should obviate or at least reduce such problems. Essentially, "pseudovirions" will be constructed corresponding to these viruses which comprise VLPs which are constituted of L1, L1 fragments, mutated forms of L1, or a combination of L1 and L2 proteins of the particular PV, and further encapsulated therein part of the genome of said papillomavirus or a DNA encoding a selectable marker.

This pseudovirion will be used in an in vitro cell "infectivity" assay to evaluate efficacy of corresponding VLP vaccines. Essentially, this will be effected by contacting cells with such pseudovirions. These pseudovirions should bind such cells and provide for the insertion of said DNA. Thereafter, insertion of said DNA may be evaluated by known methods, e.g., PCR hybridization methods, or based on the expression of the selectable marker, e.g.,  $\beta$ -galactosidase.

This will be effected both in the presence and absence of antibodies generated against L1 or L2 proteins specific to the particular HPV. If insertion is inhibited, as determined, e.g., based on reduced expression of the selectable marker, this is an indication that the L1 or L2 protein elicited production of virus-neutralizing antibodies.

The present invention is applicable for producing VLPs for any papillomavirus and in particular any human papillomavirus. Many HPV L1 and L2 DNAs have been reported in the literature and are publicly available (see, e.g., Baker, Sequence Analysis of Papillomavirus, *Genomes*, pp. 321-

384; Long et al, U.S. Pat. No. 5,437,931, Cole et al, *J. Mol. Biol.*, 193:599-608 (1987); Danos et al, *EMBO J.*, 1:231-236 (1982); Cole et al, *J. Virol.*, 38(3):991-995 (1986)). Also, it is well known that HPV L1 DNAs exhibit significant homology. Therefore, a desired HPV L1 DNA can easily be obtained, e.g., by the use of a previously reported HPV L1 DNA or a fragment thereof as a hybridization probe or as a primer during polymerization chain reaction (PCR) amplification. Indeed, numerous HPV L1 DNAs have been cloned and expressed.

Preferably, the HPV L1 DNA said in the subject invention will be derived from an HPV which is involved in cancer or condylomata acuminata, e.g., HPV-16, HPV-18, HPV-31, HPV-33, HPV-35, HPV-39, HPV-45, HPV-51, HPV-52, HPV-56, and HPV-58 are involved in cancer, and HPV-6, HPV-11, HPV-30, HPV-42, HPV-43, HPV-44, HPV-54, HPV-55, and HPV-70, are involved in warts. However, the subject homogeneous VLPs may be produced from any desired HPV L1 DNA.

In general, the selected HPV L1, L1 fragment, or mutant L1 protein, and optionally L2 sequences will be expressed in a desired recombinant host cell system, and used to produce HPV VLPs for disassembly.

The selected host and expression vector will be cultured under conditions that favor the production of VLPs. This will largely depend upon the selected host system and regulatory sequences contained in the vector, e.g., whether expression requires induction. After expression, the HPV VLPs will be extracted from the host cells. The means of extraction will also depend to some extent on the host/vector system.

For example, if an intracellular expression vector is selected, the host cells will need to be lysed and the HPV VLPs recovered from the lysate. By contrast, if the expression vector contains sequences that facilitate secretion, HPV VLPs can be recovered directly from the culture medium. Methods for recovery of heterologous proteins from recombinant host cells and culture medium are well known in the art.

HPV L1 sequences may be expressed in any host cell that provides for the expression of recoverable yields of HPV VLPs. Suitable host systems for expression of recombinant proteins are well known and include, by way of example, bacteria, mammalian cells, yeast, and insect cells. A preferred expression system comprises the baculovirus/insect cell system used in the examples as this system provides for high protein yields. However, HPV L1 and L2 proteins can be produced in other systems, in particular bacteria and yeast.

Suitable vectors for cloning of expression of the subject HPV L1, fragment or mutant thereof encoding DNA sequences are well known in the art and commercially available. Further, suitable regulatory sequences for achieving cloning and expression, e.g., promoters, polyadenylation sequences, enhancers and selectable markers are also well known. The selection of appropriate sequences for obtaining recoverable protein yields is routine to one skilled in the art.

VLPs have reported application in HPV prophylactic vaccines and diagnostics. Capsomeres produced by disassembly may also be useful, as it has been discovered that they present conformational neutralizing epitopes and induce neutralizing antibodies. The subject VLPs may be advantageous thereto because of their enhanced homogeneity, and potentially, stability.

As discussed, the present invention should be broadly applicable to any HPV L1 sequence, fragment or mutated form thereof which upon expression elicits conformational

epitopes. There are a variety of HPV types known in the art. Further, particular types of HPVs are associated with particular infections such as flat warts, cutaneous warts, epidermodysplasia verruciformis, lesions and cervical cancer. Over 60 different HPV types have been identified in clinical lesions by viral nucleotide sequence homology studies. See, for example, Jenson et al, In: Belshe, R. ed., Textbook of human virology, Second Edition, MASS:PSG, 1989:951 and Kremsdorf et al, *J. Virol.*, 52:1013-1018 (1984). The HPV type determines, in part, the site of infection, the pathological features and clinical appearance as well as the clinical course of the respective lesion.

Because it is believed that there is little or no cross-immunity for HPV types and immunity to infection is HPV type-specific, it will be necessary to produce recombinant HPV VLPs for each specific HPV type upon which protection or treatment is needed. However, due to the homology between the L1 proteins and genes, hybridization techniques can be utilized to isolate the particular L1 gene of interest. Nucleotide probes selected from regions of the L1 protein which have been demonstrated to show sequence homology, can be utilized to isolate other L1 genes. Methods for hybridization are known in the art (see, for example, *Nucleic Acid Hybridization, A Practical Approach*, IRL Press, Washington, D.C. (1985); *Molecular Cloning, A Laboratory Manual*, Maniatis et al, eds., Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y. (1982); and *Molecular Cloning, A Laboratory Manual*, Sambrook et al, eds., Cold Spring Harbor Laboratory, Second Edition, Cold Spring Harbor, N.Y. (1989)). Alternatively, PCR methods can be utilized to amplify L1 genes or gene fragments (see, e.g., U.S. Pat. Nos. 4,683,195; 4,683,202; and 4,800,159).

Virus particles can also be isolated for a particular papillomavirus type, the DNA cloned, and the nucleic acid sequences encoding L1 proteins isolated. Methods for isolation of viral particles and cloning of virus DNAs have been reported (see, e.g., Heilman et al, *J. Virology*, 36:395-407 (1980); Beaudenon et al, *Nature*, 321:246-249 (1986); Georges et al, *J. Virology*, 51:530-538 (1984); Kremsdorf et al, *J. Virology*, 52:1013-1018 (1984); Clad et al, *Virology*, 118:254-259 (1982); DeVilliers et al, *J. Virology*, 40:932-935 (1981); and European Patent Application 0,133,123).

Alternatively, the L1 protein for a particular human papillomavirus can be isolated, the amino acid sequence determined and nucleic acid probes constructed based on the predicted DNA sequence. Such probes can be utilized in isolating the L1 gene from a library of the papillomavirus DNA (see, e.g., Suggs et al, *PNAS*, 78(11):6613-6617 (1981) and Young and Davis, *PNAS*, 80:1194(1983)).

As discussed, VLP formation is somewhat sensitive to the cell type wherein expression is effected. Therefore, it is advantageous to select systems which produce large quantities of VLPs as the starting material for VLP disassembly. Generally, the expression system will comprise a vector having the L1 protein of interest and the appropriate regulatory regions as well as a suitable host cell.

Baculovirus vectors are a preferred vector system. The baculovirus system offers the advantage that a large percentage of cells can be induced to express protein due to the use of infection rather than transfection techniques. While baculovirus is an insect virus and grows in insect cells (Sf9), these cells contain many of the eucaryotic mechanisms for processing of proteins including glycosylation and phosphorylation which may be important for generating proteins of appropriate conformation. Baculovirus vector systems are known in the art (see, e.g., Summers and Smith, *Texas Agricultural Experimental Bulletin*, No. 1555 (1987); Smith

et al, *Mol Cell Biol.*, 3:2156-2165 (1985); Posse, *Virus Research*, 5:4359 (1986); and Matsuura, *J. Gen. Virol.*, 68:1233-1250 (1987)). Also, it has been reported that baculovirus infected cells express HPV L1 proteins exhibiting the appropriate conformation.

For expression in an appropriate expression system, an L1 gene, fragment or modified L1 gene is operably linked into an expression vector and introduced into a host cell to enable the expression of the L1 protein by that cell. The gene with the appropriate regulatory regions will be provided in the proper orientation and reading frame to allow for expression. Methods for gene construction are known in the art. (see, in particular, *Molecular Cloning, A Laboratory Manual*, Sambrook et al, eds., Cold Spring Harbor Laboratory, Second Edition, Cold Spring Harbor, N.Y. (1989)), and the references cited therein.

A wide variety of transcriptional and regulatory sequences may be employed. The signals may be derived from viral sources, where the regulatory signals are associated with a particular gene which has a high level of expression. That is, strong promoters, for example, of viral or mammalian sources, will be utilized. In this manner, the optimum conditions for carrying out the invention include the cloning of the L1 gene into an expression vector that will overexpress conformationally-dependent virus-neutralizing epitopes of the L1 protein in transfected or infected target cells.

The suitability of the HPV VLPs produced according to the invention as vaccines or as diagnostic agents is confirmed by reaction with antibodies or monoclonal antibodies which react or recognize conformational epitopes present on the intact virion and based on their ability to elicit the production of neutralizing antiserum. Suitable assays determining whether neutralizing antibodies are produced are known to those skilled in the art. This is an essential characteristic of HPV VLPs which are to be used in HPV vaccines. In this manner, it can be verified whether the HPV VLPs will elicit the production of anti-HPV neutralizing antibodies. Thus, other expression vectors and expression systems can be tested for use in the invention.

As discussed, the VLPs of the present invention can be utilized to detect, diagnose, serotype, and treat papillomavirus infection. When used for diagnosis or serotyping, VLPs according to the invention may be labeled using any of a variety of labels and methods of labeling. Examples of types of labels which can be used in the present invention include, but are not limited to, enzyme labels, radioisotopic labels, non-radioactive isotopic labels, fluorescent labels, toxin labels, and chemiluminescent labels.

Examples of suitable enzyme labels include malate dehydrogenase, staphylococcal nuclease, delta-5-steroid isomerase, yeast-alcohol dehydrogenase, alpha-glycerol phosphate dehydrogenase, triose phosphate isomerase, peroxidase, alkaline phosphatase, asparaginase, glucose oxidase, beta-galactosidase, ribonuclease, urease, catalase, glucose-6-phosphate dehydrogenase, glucoamylase, acetylcholinesterase, etc.

Examples of suitable radioisotopic labels include  $^3\text{H}$ ,  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $^{32}\text{P}$ ,  $^{35}\text{S}$ ,  $^{14}\text{C}$ ,  $^{51}\text{Cr}$ ,  $^{57}\text{Co}$ ,  $^{58}\text{Co}$ ,  $^{59}\text{Fe}$ ,  $^{75}\text{Se}$ ,  $^{152}\text{Eu}$ ,  $^{90}\text{Y}$ ,  $^{67}\text{Cu}$ ,  $^{211}\text{Pb}$ ,  $^{47}\text{Sc}$ , and  $^{109}\text{Pd}$ .

Examples of suitable fluorescent labels include a  $^{152}\text{Eu}$  label, a fluorescein label, an isothiocyanate label, a rhodamine label, a phycoerythrin label, a phycocyanin label, an allophycocyanin label, an o-phthalaldehyde label, a fluorescamine label, etc.

Examples of suitable toxin labels include diphtheria toxin, ricin, and cholera toxin. Examples of chemiluminescent

labels include a luminal label, an isoluminal label, an aromatic acridinium ester label, an imidazole label, and acridinium salt label, an oxalate ester label, a luciferin label, a luciferase label, an aequorin label, etc.

Those of ordinary skill in the art will know of other suitable labels which may be employed in accordance with the present invention. The binding of these labels to VLPs can be accomplished using standard techniques commonly known to those of ordinary skill in the art. Typical techniques are described by Kennedy et al, *Clin. Chim. Acta*, 70:1-31 (1976), and Schurs et al, *Clin. Chim. Acta*, 81:1-40 (1977). Coupling techniques mentioned in the latter are the glutaraldehyde method, the periodate method, the dimaleimide method, the m-maleimidobenzyl-N-hydroxy-succinimide ester method—all these methods incorporated by reference herein.

The detection of the anti-HPV antibodies using the subject VLPs can be improved through the use of caters. Well-known caters include glass, polystyrene, polypropylene, polyethylene, dextran, nylon, amylases, natural and modified celluloses, polyacrylamides, agaroses and magnetite. The nature of the carrier can be either soluble to some extent or insoluble for the purposes of the present invention. Those skilled in the art will note many other carriers suitable for binding proteins, or will be able to ascertain the same by use of routine experimentation.

The most important aspect of the present invention, however, involves the development of PV vaccines. The vaccines of the invention will contain an amount of the subject HPV VLPs sufficient to induce formation of neutralizing antibodies in the host contained in a pharmaceutically acceptable carrier.

Administration of the subject VLP-containing vaccines may be effected by any pharmaceutically acceptable means, e.g., parenterally, locally or systemically, including by way of example, oral, intranasal, intravenous, intramuscular, and topical administration. The manner of administration depends on factors including the natural route of infection. The dosage administered will depend upon factors including the age, health, weight, kind of concurrent treatment, if any, and nature and type of the particular human papillomavirus. The vaccine may be employed in dosage form such as capsules, liquid solutions, suspensions, or elixirs, for oral administration, or sterile liquid formulations such as solutions or suspensions for parenteral or intranasal use. An inert, immunologically acceptable cater is preferably used, such as saline or phosphate buffered saline.

The vaccines will be administered in therapeutically effective amounts. That is, in amounts sufficient to produce a protective immunological response. Generally, the vaccines will be administered in dosages ranging from about 0.1 mg protein to about 20 mg protein, more generally about 0.001 mg to about 100 mg protein. Single or multiple dosages can be administered.

The method of the present invention makes possible the preparation of HPV VLPs containing vaccines for preventing papillomavirus infection. Further, by following the methods of the invention, vaccines for any of human specific papillomavirus can be made.

As more than one PV type may be associated with PV infections, the vaccines may comprise stable HPV VLPs derived from more than one type of PV. For example, as HPV 16 and 18 are associated with cervical carcinomas, therefore a vaccine for cervical neoplasia may comprise VLPs of HPV 16; of FIPV 18; or both HPV 16 and 18.

In fact, a variety of neoplasia are known to be associated with PV infections. For example, HPVs 3a and 10 have been

associated with flat warts. A number of HPV types have been reported to be associated with epidermodysplasia verruciformis (EV) including HPVs 3a; 5, 8, 9, 10, and 12. HPVs 1, 2, 4, and 7 have been reported to be associated with cutaneous warts and HPVs 6b, 11a, 13, and 16 are associated with lesions of the mucus membranes (see, e.g., Kremsdorff et al, *J. Virol.*, 52:1013-1018 (1984); Beaudenon et al, *Nature*, 321:246-249 (1986); Heilman et al, *J. Virol.*, 36:395-407 (1980); and DeVilliers et al, *J. Virol.*, 40:932-935 (1981)). Thus, the subject vaccine formulations may comprise a mixture of reassembled VLPs derived from different HPV types depending upon the desired protection.

As indicated, the HPV VLPs of the invention can also be utilized for serotyping and for incorporation in serotyping kits.

For serological testing, the kits will comprise the subject HPV VLPs and means for detection such as enzyme substrates, labelled antibody, and the like.

Having now generally described the invention, the following examples are offered by way of illustration and not intended to be limiting unless otherwise specified.

## EXAMPLES

The following materials and methods were used in the Examples.

### Materials and Methods

#### HPV-11 VLPs

For use in studies of VLP-disassembly and reassembly using pure protein, HPV-11 L1 proteins were heterologously expressed in *Trichoplusia ni* (High Five®) cells infected with recombinant baculovirus encoding the complete L1 open reading frame downstream of the polyhedrin promoter as described (Ghim et al, In M. A. Stanley (ed.) *Immunology of human papillomaviruses*, Plenum, New York, p. 147-153 (1993)). Cells were harvested approximately 72 hours post-infection, pelleted by centrifugation, and frozen. For preparation of VLPs, the cell paste was resuspended in homogenization buffer (20 mM NaH<sub>2</sub>PO<sub>4</sub>, 150 mM NaCl, pH 7.4, containing 10- $\mu$ g/ml leupeptin, 1  $\mu$ g/ml aprotinin, and 1  $\mu$ g/ml pepstatin A) and lysed in a microfluidizer (Microfluidics model HC8000/3A). The homogenized lysate was then centrifuged at 100,000 $\times$ g for 90 minutes and the pellet containing HPV-11 VLPs was resuspended in PBS containing CsCl (405 g/L). The clarified lysate was then centrifuged overnight at 83,000 $\times$ g, and the VLP band was collected. The VLPs were diluted in PBS-0.5M NaCl, and layered over a two component step gradient composed of 30% and 63% sucrose. The gradients were centrifuged at 167,000 $\times$ g for 3 hours, and the purified VLP band was collected at the interface between the 30% and 63% sucrose solutions. The VLPs were then dialyzed into selected buffers (either PBS, or PBS with NaCl added to a final concentration of 0.3 M or 0.5 M), and stored at 4° C. Protein concentration was determined by the Bradford assay (Bradford et al, *Anal. Biochem.*, 72: 248-254 (1976)) using bovine serum albumin as the reference protein, and L1 content was determined as described (Suzich et al, *Proc. Natl. Acad. Sci. USA*, 92: 11553-11557 (1995)). Starting with 25-30 g of wet cell paste, the above protocol yielded 15-25 mg of HPV-11 VLPs.

#### HPV-16<sub>Tr</sub> VLPs

For use in studies of VLP-disassembly and reassembly during purification, HPV-16<sub>Tr</sub> L1 proteins (composed of a mutated form of the HPV-16 L1 protein from which the

C-terminal 34 amino acids have been deleted) were expressed in High Five® cells as described above. The cell paste was resuspended in extraction buffer (10 mM Tris, 1.0% Triton X-100, pH 6.0), mixed by stirring, and centrifuged briefly at 1,000×g. The pellet containing the HPV-167 VLPs was resuspended in 20 mM Tris, 0.1 M NaCl, pH 8.0 buffer, vortexed briefly, and centrifuged at 3,000×g for 30 min. The supernatant was collected, filtered through 0.45 µ cellulose acetate syringe filters, and then incubated in the presence or absence of 4% BME for >2 hours at 4° C. prior to use in column purification trials. The clarified, filtered supernatant (+/-13ME) was applied to different ion exchange resins at low conductivity values (5-15 milliohms), washed with several column volumes of equilibration buffer and eluted with a gradient of increasing NaCl. To test the utility of HIC to remove residual DNA and protein contaminants, the fractions containing the peak of the eluted L1 protein from IEC were pooled, adjusted to 0.7 M in ammonium sulfate and applied to an HIC column equilibrated in the same buffer. The column was washed with several column volumes of equilibration buffer, and then the L1 protein was eluted from the HIC column at lower ammonium sulfate concentration. The final products of the purification processes (+/- βME) were dialyzed extensively against PBS (0.5M NaCl), and compared in terms of purity, yield, and residual DNA. The appearance of the VLPs was characterized by electron microscopy and linear sucrose gradient analysis (see below).

#### Sucrose Gradient Centrifugation

Three types of sucrose gradients were used in these experiments. First, centrifugation on 30% sucrose cushions was used to identify conditions which favored the disassembly of VLPs into smaller, soluble components. 100-200 µl reaction mixtures containing VLPs (50-100 µg total protein) plus or minus potential disrupting agents were layered atop 5 ml centrifuge tubes filled with 4.8 ml of 30% sucrose (w/v in PBS-0.5M NaCl) and centrifuged at 197,000×g for 2 hours at 40°C in a swinging bucket rotor. A 50 p.l aliquot was taken from the very top of the tube, and mixed with 2x Laemmli sample preparation buffer (Laemmli, U.K., *Nature*, 227:680-685 (1970)). The remainder of the 30% sucrose cushion was removed by pipet, and the "pellet" (typically none was visible) was resuspended in 100 p.l of 1x Laemmli sample preparation buffer. The presence of HPV-11 L1 protein at the top or bottom of the 30% sucrose cushion was then determined by SDS/PAGE, and the relative amount of L1 quantified by analysis of digitized gels. Second, the state of disassembled VLPs was determined by rate-zonal centrifugation through 5-20% linear sucrose gradients. Disassembled VLPs (100-200 µg total protein in 400 p.l) were layered atop preformed 11.6 ml gradients composed of 5-20% sucrose (w/v in PBS-0.5M NaCl), and centrifuged at 111,000×g for 24 hours at 4° C. in a swinging bucket rotor. Fractions (0.5 ml) were collected across the gradient, and the "pellet" (typically none was visible) was resuspended in 0.5 ml of PBS by gentle homogenization. The position of HPV-11 L1 protein across the gradient was determined by immunoblotting. The gradients were calibrated using standard proteins with established sedimentation coefficients (*E. coli* B-galactosidase, 19 S; bovine liver catalase, 11.3 S; bovine serum albumin, 4.3 S), and the percentage of sucrose in the fractions was determined by refractometry.

Third, the state of initial, disassembled, and reassembled VLPs was determined by rate-zonal centrifugation through 10-65% linear sucrose gradients. HPV-11 L1 protein (100-

200 µg total protein in 400 µl) in various states of assembly was layered atop preformed 11.6 ml gradients composed of 10-65% sucrose (w/v in PBS-0.5M NaCl), and centrifuged at 188,000×g for 2.5 hours at 40° C. in a swinging bucket rotor. The gradients were collected (in 1.0 ml fractions), analyzed, and calibrated as above, with parvovirus B 19 (705) and HPV-18 L1 VLPs (160 S) used as additional calibration standards.

#### Gel/Electrophoresis

##### SDS/PAGE

SDS/PAGE was performed largely according to the method of Laemmli (Laemmli, U.K., *Nature*, 227: 680-685 (1970)). Samples were mixed with sample preparation buffer, boiled for 2 minutes, briefly spun in a minifuge, and loaded onto 7.5% (FIG. 1) or 10% (FIGS. 2-4) minigels with a 4% stacking gel. Gels were run for approximately 1 hour at 20 mA constant current at room temperature, and protein was visualized by staining with Coomassie brilliant blue R250.

##### Immunoblotting

Electroblots of HPV-11 L1 from SDS/PAGE gels were prepared largely according to the method of Towbin et al (*Proc. Natl. Acad. Sci. USA*, 76: 4350-4354 (1979)). The blots were blocked with 1% nonfat milk protein in PBS overnight at 4° C. The blots were probed with AU1 (Berkely Antibody Co.), a mouse monoclonal directed against a linear epitope on papillomavirus L1 proteins (25) for 90 minutes, washed with PBS, 0.1% Triton X-100, and then reblocked for 30 minutes. The blots were then incubated with HRP-labeled goat anti-mouse IgG (Southern Biotechnology Associates, Inc.) for 40 minutes, and washed as above. The blots were then developed with ECL Western blotting reagent (Amersham), and exposed to X-ray film.

##### Analysis of Gels

The  $M_r$  of monomeric and oligomeric L1 were determined from their  $R_f$  values on 7.5% SDS/PAGE, in comparison to standard proteins (See, Jackowski et al, In T. E. Creighton (ed.), *Protein structure: a practical approach*, IRL Press, New York, p 1-21 (1989)). When indicated, gels were digitized on a Hewlett Packard Scanjet Plus flatbed densitometer, and the relative intensity of bands was determined using Scan Analysis software (Version 2.2; Specrom Research).

##### Electron Microscopy

Protein samples were allowed to settle on formvar- and carbon-coated copper grids (Electron Microscopy Sciences), blotted dry, and stained with freshly-filtered 2% phosphotungstic acid (pH 6.8). Grids were examined in a JEOL model 1005 transmission electron microscope at an accelerating voltage of 100 KV and photographed at nominal magnifications of 15-25,000×.

##### Enzyme-linked Immunosorbent Assay (ELISA)

HPV-11 L1 VLPs (0.5-1.0 mg/ml L1) in PBS-0.3 M NaCl were either stored without treatment at 4° C., or incubated overnight at 4° C. following addition of 13ME (to a final concentration of 5%) or 2.0 M carbonate buffer, pH 9.6 (to a final concentration of 200 mM carbonate). A portion of the treated samples were then dialyzed against 4x1L PBS-0.5 M NaCl at 4° C. for ≥24 hs. All samples were diluted to a concentration of 0.8 µg L1/ml and distributed into the wells of microtiter plates (80 ng L1 per well). Untreated VLPs and dialyzed material were diluted into PBS. The sample treated with 13ME without subsequent dialysis was diluted into PBS

containing 5% j3ME, and undialyzed sample incubated in 200 mM carbonate was diluted into 200 mM carbonate, pH 9.6. Following incubation at 37° C. for 1 hr, the plates were washed with PBS, 0.1% Tween -20 (PBS-Tw) and blocked with 5% nonfat milk protein in PBS. Monoclonal antibodies (AU 1, or H ii .F 1 and H ii .A3 purified from ascites purchased from Pennsylvania State University (Christensen et al, 1 *ViroL*, 64:5678-5681 (1990)), were diluted in 1% nonfat milk in PBS and added to the wells. Following a 2 hr incubation at room temperature, the plates were washed with PBS-TW and HRP-labeled goat antimouse IgG was added. After 1 hr at room temperature, the plates were washed as above and developed with HRP substrate (Kirkegaard and Perry Laboratories). Optical density measurements were made at 405 nm at the 15 mm endpoint. Averages of duplicate wells were calculated as the final optical density values.

#### HPV-11 Neutralization Assay

Antisera against original purified HPV-11 VLPs, and HPV-11 VLPs which were disassembled by prolonged exposure to sulphydryl reducing agent and then reassembled upon removal of the reducing agent by dialysis, were generated in BALB/c mice (groups of 5). The mice were injected s.c. with 1 µg of VLPs adsorbed to 1 mg/ml alhydrogel adjuvant at weeks 0, 4, and 9, with terminal bleeds performed on week 13. To determine whether the antisera raised in the mice was able to neutralize HPV-11 virus, the ability of the antisera to block the expression of a specific HPV-11 spliced mRNA in a human cell line (HaCaT) was tested.

HaCaT, an immortalized human keratinocyte cell line (Boukamp et al, 1 *Cell Biol*, 106: 761-771 (1988)) were provided by Dr. Norbert Fusenig. Cells were grown to confluency in 1 54/HKGS (Cascade Biologics, Inc.) supplemented with penicillin (100 units/ml) and streptomycin (100 p.g/ml) in 24 well plates, HPV-11 <sup>Harshay</sup> stock virus, purchased from Dr. John Kreider (Kreider et al, 1. *ViroL*, 61:590-593 (1987)), was sonicated for 25 sec on ice, diluted in 1 54/HKGS medium, and incubated for one hour at 37° C. Medium was aspirated from the HaCaT cells and 0.5 ml of diluted virus was added per well. As a control, one well of cells on each plate received 0.5 ml of medium without virus. For antibody-mediated neutralization, antisera were diluted in 1 54/HKGS and incubated with a fixed quantity of the HPV-11 stock virus in a final volume of 0.5 ml for one hour at 37° C. prior to addition to the HaCaT cells. Fresh medium was added to each well of cells four days post-infection, and on day six cells were harvested and total cellular RNA was prepared using Tri Reagent (Molecular Research Center, Inc.). Final RNA pellets were resuspended in 20 p.l of DEPC-treated water and quantified by spectrophotometry.

The ability of the antisera to block the expression of HPV-11-specific spliced mRNA was determined by reverse-transcriptase (RT)-PCR. RT reactions were performed using a First Strand cDNA kit (Boehringer Mannheim) with 2 µg of total RNA as the template and oligo dT as the primer. Nested PCR was needed to detect HPV-11 E1 AE4 cDNA. The first round of amplification was carried out with 25% of the cDNA from each RT reaction and 5'-TACAAGAC-CTTTTGCTGGGCACA3' (located at bases 765-787 in the HPV-11 genomic sequence) as the forward outside primer and 5'-AAAGGCAGGAAAATAGCACAC3' (located at bases 4088-4110 in the HPV-11 genomic sequence) as the reverse outside primer for 30 cycles of PCR. Ten percent of the first round PCR mixture was used for nested reactions

with 3 5'-ATATTGTGTGTCCCATCTGCG3' (located at bases 792-812 as nested forward primer and 5'-CAG-CAATTGTACAGGCACTAC-3' (located at bases 3877-3898 in the HPV-11 genomic sequence) as the nested reverse primer for 30 cycles of PCR. First round and nested PCR reactions were set up with Hot Wax beads (1.5 mM) and pH 9.5 buffer (Invitrogen) with 200 p.M dNTPs, 125 ng each forward and reverse primer, and 2.5 units of Taq polymerase (Perkin-Elmer) in a final volume of 50 p.l. The temperature profile for both first round and nested PCR was 800 C/S mm, 950 C/30 sec, 72° C/30 sec, with a final extension at 720 C for 10 mm.

As a control to demonstrate that the assay was able to detect niRNA extracted from HaCaT cells, all cDNA samples were used in separate PCR reactions with primers specific for spliced cellular B-actin mRNA as described and amplified as above (Smith et al, 0.1 *Invest Dermatol*, 105: 1-7) (1995).

All PCR products were separated by electrophoresis on a 20 2% agarose gel and visualized by ethidium bromide fluorescence.

#### Example 1

##### Quantitative Disassembly of HPV-11 VLPs

Relatively large quantities of HPV-11 L1 VLPs were prepared as starting material for the study of VLP disassembly and reassembly. HPV-11 L1 VLPs were isolated from recombinant baculovirus-infected High Five® cells by -CsCl and sucrose gradient centrifugation. The calculated purity of these L1 preparations, based on densitometric analysis of SDS/PAGE, ranged between 70-90% (see FIG. 1, lane 2). In addition, in linear sucrose gradients most of the protein migrated as expected for a mixture of individual and clumped VLPs (FIG. 4a), and in the electron microscope a mixture of intermediate and full-size (50-55 nm) particles were apparent (FIG. 5a).

The covalent and non-covalent interactions which stabilize the assembled L1 VLPs are not entirely known, but earlier work on papillomavirus VLPs and related polyomavirus virions and VLPs suggested the importance of ionic strength, divalent cations (Brady et al, 1 *ViroL*, 23:717-724 (1977); Salunke et al, *Biophys. J*, 56:887-900 (1987), and disulfide bonds (Sapp et al, *J. Gen. Virol*, 76:2407-2512 (1995); Volpers et al, *Virology*, 200:504-512 (1994)). In particular, Sapp and co-workers had demonstrated by immunoblotting that ~50 percent of the L1 protein of HPV-33 VLPs was disulfide-bonded into a range of larger oligomers with an apparent M<sub>r</sub> consistent with trimers of L1, and that mild reducing conditions partially broke down HPV-33 VLPs to the level of capsomeres (Sapp et al, 1 *Gen. Virol*, 76:2407-2412 (1995); Volpers et al, *ViroL*, 200:504-512 (1994)). In our studies, in the absence of reducing agents only a portion of the HPV-11 L1 protein migrated on SDS/PAGE with an apparent M of 55,000 Da (FIG. 1, Lane 1). Approximately 40% (the percentage varied between different VLP preparations) of the L1 protein of HPV-11 VLPs was disulfide-bonded into larger oligomers (FIG. 1, Lane 1), with predicted M<sub>r</sub> values of approximately 144,000 Da (possibly L1 trimer) and 210,000 Da possibly L1 tetramer). The L1 oligomers did not migrate as a single band, and appeared to be heterogeneous in size. The ~200,000 Da oligomer was also observed on immunoblots by Sapp and coworkers (Sapp et al, 1 *Gen. Virol*, 76:2407-2412 (1995); Volpers et al, *ViroL*, 200:504-512(1994)), as part of a broad higher molecular weight band. These results indicate that a

portion of the L1 proteins in HPV-11 VLPs are disulfide-linked into higher oligomers. To study the role of disulfide linkages and other interactions in VLP stability, a rapid screening assay for VLP disassembly was developed. Purified HPV-11 L1 VLPs, both before and after various treatments, were layered atop 30% sucrose cushions, centrifuged, and the distribution of L1 protein at the top and bottom of the 30% cushion was visualized by SDS/PAGE. Intact VLPs were expected to pellet though the 30% sucrose cushion; non-aggregated capsomeres and L1 monomer were expected to remain on the top of the cushion. An example of this assay is shown in FIG. 2. To quantitate the relative disposition of L1 protein, the gels were digitized, the total intensity of the L1 bands at the top and the bottom of the cushion was determined, and then the percentage of the L1 staining intensity found at either position was calculated. The results of a number of such determinations are tabulated in Tables 1 and 2. As demonstrated in FIG. 2, the purified VLP starting material sedimented though the 30% sucrose, as predicted, with no L1 apparent at the top. However, upon incubation with a high concentration of the reducing agent  $\beta$ -mercaptoethanol (B-ME), L1 protein was found largely at the top of the 30% sucrose cushion, indicating that the reducing agent had disassembled the HPV-11 VLPs to smaller, non-aggregated components. Interestingly, maximal disassembly of the VLPs typically required exposure to a very high concentration of reducing agent (in this instance 5%, or 713 mM,  $\beta$ ME) for a relatively long duration (~16 hours at 4° C.). Lower concentrations of reducing agent or shorter durations of reduction were not as reliably effective at VLP disassembly. Addition of a low concentration of a chelating agent did not enhance disassembly (FIG. 2 and Table 1).

In addition to reductants, the other important variables for quantitative disassembly of VLPs were found to be the ionic strength during the disassembly reaction and the solubility of the VLP starting material. As observed earlier for polyomavirus virions, lower ionic strength conditions destabilize VLPs (Brady et al, *J. Virol.*, 23:717-724 (1977)), although Sapp et al, *J. Gen. Virol.*, 76:2407-2412 (1996) reported that generation of HPV-33 capsomeres from VLPs was insensitive to salt concentration between 0.15 M and 0.6 M NaCl. For HPV-11 VLPs, maximum disassembly (~90%) of VLPs exposed to 5% PME for 16 hours was observed at "physiological" ionic strength (i.e., 0.15 M NaCl), but became correspondingly less effective as the ionic strength was increased (Table 1). The stabilizing effect of increased ionic strength could be partially overcome by incubating the VLPs with reducing agents for longer durations or at elevated temperatures. However, while incubating the VLPs with 5%  $\beta$ ME for 120 hours at 4° C., or for 24 hours at 24° C. increased the extent of disassembly to 60-70% at 0.5 M NaCl, disassembly was still far from complete (data not shown). Furthermore, for quantitative disassembly, the degree of aggregation of the VLP starting material was also important. In the experiments reported here, the VLP solutions were dialyzed into different ionic strength buffers and stored at 4° C. until use in disassembly trials. After several days, particularly at 0.15 M NaCl, the solutions became slightly cloudy, indicating some degree of aggregation (although little or no precipitate was observed). Treatment of the clouded VLP solutions with reducing agents did not yield the same degree of disassembly as was observed with the initial soluble VLP solution, indicating that the aggregated VLPs were resistant to disassembly. However, upon removal of the aggregated material (which ranged from 10-50% of the total VLPs depending on the age of the

preparation) by filtration, the remaining soluble VLPs again could be disassembled to the same extent as the initial soluble VLP starting material.

Interestingly, even at high concentrations of chelators, chelation of cations did not significantly influence VLP disassembly. Dialysis of VLPs into 200 mM EDTA or EGTA buffers (PBS-0.3 M NaCl, pH 7.4) led to no apparent disassembly, and the addition of 10 mM dithiothreitol (DTT) to the dialysis buffers had little effect (Table 2). The inability of high concentrations of chelators to disassemble VLPs was confirmed by electron microscopic analysis, although EDTA (but not EGTA) appeared to swell the VLPs slightly (data not shown). Either these concentrations of chelator are insufficient to extract tightly bound, structurally-important ions, or cations are not essential to maintaining VLP structural integrity. Conversely, addition of a concentrated aliquot of NaHCO<sub>3</sub> buffer (pH 9.6) to a solution of VLPs, to a final concentration of 200 mM carbonate (in PBS-0.3 M NaCl), caused significant breakdown of the VLPs (Table 2). Addition of DTT (to a final concentration of 10 mM), did not further enhance carbonate-induced breakdown. Incubation of VLPs with 200 mM carbonate/b mM DTT is commonly used to denature HPV virions or VLPs in ELISAs (Favre et al, *J. Virol.*, 15:1239-1237 (1975); Christensen et al, *J. Virol.*, 64:3151-3156 (1990); Christensen et al, *J. Gen. Virol.*, 75:2271-2276 (1994)). The effect of carbonate appears to be buffer specific, and not merely a function of pH, as incubation of HPV-11 VLPs with pH 9.6 glycine buffer (200 mM final concentration) caused very little VLP breakdown, as measured by the 30% sucrose cushion assay (Table 2). Similarly, Brady et al (*J. Virol.*, 23:717-724 (1977)), observed that carbonate buffer at alkaline pH, but not alkaline pH alone, dissociated polyomavirus virions. However, the specific effect of carbonate at pH 9.6 does not appear to be due to carbonate's potential chelating ability, as suggested by Brady et al (*J. Virol.*, 23:717-724 (1977)), as 200 mM EDTA at pH 9.6 (+1-10 mM DTT) was completely ineffective at VLP disassembly (data not shown).

## Example 2

### Characterization of Disassembled HPV-11 VLPs

Following long-term exposure to high concentrations of reducing agent, the purified VLPs appear to be broken down to the level of capsomeres. As shown in FIG. 3a, the disassembled VLPs generated by incubation with 5%  $\beta$ ME for 16 hours at 4° C. migrated on 5-20% linear sucrose gradients with an average sedimentation coefficient of  $11.3 \pm 1.5$  S (n=5), determined relative to sedimentation standards. Larger species, with a calculated sedimentation coefficient of 16-18 S (perhaps dimeric capsomeres), and even pelleted materials were occasionally observed. However, less than 10% of the L1 was detected at the top of the gradient (expected position for L1 monomer) or in the pellet (expected position for intact VLPs or aggregated capsomeres), suggesting that the purified VLP starting material was largely disassembled to the level of individual capsomeres upon prolonged reduction. This conclusion is supported by electron microscopic analysis of VLPs following prolonged incubation with 5% B-ME, which depicted a field of homogeneous capsomeres (FIG. 5b) averaging  $9.7 \pm 1.2$  nm (n=15) in diameter, with occasionally a few larger aggregated structures apparent (monomeric L1 would not be detected with this technique). The estimated capsomere diameter is slightly smaller than that observed by cryoelectron microscopy (11-12 nm) (Baker et al, *Biophys. J.*, 60:1445-1456

(1991); Hagensee et al, *J. Virol.*, 68:4503-4505, (1994); Belnap et al, *Mol. Biol.*, 259:249-263 (1996)), perhaps due to shrinkage during electron microscope grid preparation. The data demonstrated in FIGS. 3a and 3b indicate that prolonged exposure to high concentrations of reductants quantitatively disassembles purified, soluble VLPs to a homogenous population of capsomeres.

Capsomeres generated from HPV-11 VLPs upon long term exposure to high concentrations of reducing agent contain structural epitopes found on intact VLPs. A panel of HPV-11-specific monoclonal antibodies has been described which react with intact HPV-11 L1 VLPs but not with "denatured" L1. These monoclonals include H11.F1, which has been demonstrated to recognize a dominant neutralizing epitope on HPV-11 virions, and H11.A3, a distinct non-neutralizing structure-dependent antibody (Christensen and Kreider, *J. Virol.*, 64:3151-3156 (1990); Christensen et al, *J. Virol.*, 64:5678-5681 (1990)). As anticipated, H11.F1 and H11.A3 reacted strongly with the purified HPV-11 VLP starting material when analyzed by ELISA (FIG. 6a). However, these antibodies also reacted with capsomeres generated from the VLP starting material by exposure to reducing agent (FIG. 6b). Thus, capsomeres possess at least some of the structure-dependent epitopes found on the surface of intact VLPs and authentic virions, in agreement with studies performed by Li et al, (*J. Virol.*, 71:2988-2995 (1997)) on HPV-11 capsomeres expressed in *E. coli*. These results further demonstrate that monoclonal antibodies H11.F1 and H11.A3, while requiring a "native-like" conformation for binding, are not VLP-dependent as has been previously described (Ludmerer et al, *J. Virol.*, 71:3834-3839 (1997)).

By contrast, monoclonal antibodies H11.F1 and H11.A3 fail to recognize HPV 11 VLPs dissociated by treatment with carbonate buffer at pH 9.6 (data not shown; Christensen et al, *Gen. Virol.*, 75:2271-2275 (1994)). Carbonate treatment did not lead to a homogeneous solution of capsomeres, but instead appeared as an indistinct mixture of small objects, partially aggregated, when examined by electron microscopy (data not shown). This view was partially confirmed by analysis of carbonate-treated VLPs on 5-20% linear sucrose gradients, in which the L1 protein largely migrated at ~4 S, although a small population at 9-11 S was observed (FIG. 3b), in agreement with the effects of carbonate buffer (at pH 10.6, with 10 mM DTT) upon BPV virions (Favre et al, *J. Virol.*, 15:1239-1247 (1975)). Finally, while treatment with glycine buffer at pH 9.6 did not dissociate VLPs to smaller, individual particles (Table 2), it did have some effect. VLPs treated with pH 9.6 glycine appeared in the electron microscope as a poorly-defined mixture of intact, and partially-broken down and aggregated VLPs (data not shown).

### Example 3

#### Quantitative Reassembly of HPV-11 VLPs

VLP reassembly from HPV-11 capsomeres occurred upon removal of reducing agent, either by dialysis or column chromatography. Starting with a homogeneous preparation of soluble capsomeres, prolonged dialysis in the absence of reducing agents consistently yielded a defined population of reassembled VLPs (FIGS. 4c and 5c,d). The reassembled VLPs retained the structural epitopes recognized by monoclonal antibodies H11.F1 and H11.A3 (FIG. 6c).

For reassembly, capsomeres (1-5 ml at 0.5-1.0 mg/ml total protein) were dialyzed versus 4x1 L PBS-0.5M NaCl at 4°

C. for >24 hrs; the elevated salt concentration was designed to stabilize the VLPs. Whereas the addition of chelating agents did not appreciably enhance the ability of reducing agents to disassemble VLPs (Table 1), the presence of 2 mM EDTA moderately interfered with reassembly, yielding VLPs which migrated on a 10-65% linear sucrose gradient as a fairly discrete population of 150 S particles but appeared flattened and partially opened-up in the electron microscope (data not shown). Conversely, the addition of 2 mM Ca<sup>2+</sup> during the reassembly reaction caused the VLPs to adhere to one another, as shown by 10-65% linear sucrose gradient analysis, in which VLPs reassembled in the presence of calcium migrated entirely in the pellet. However, the presence of Ca<sup>2+</sup> did not otherwise appear to influence basic VLP morphology when examined in the electron microscope (data not shown). Finally, dialysis of carbonate-treated VLPs into PBS-0.5 M NaCl did not lead to the reassembly of VLPs. Instead, L1 protein remained as either small, soluble components or amorphous, aggregated precipitate, as evidenced by both electron microscopic and 10-65% linear-sucrose gradient analysis (data not shown). Dialysis of carbonate-treated VLPs failed to restore reactivity with structure-specific monoclonal antibodies H11.F1 and H11.A3 (FIG. 6d).

#### Characterization of Reassembled HPV-11 VLPs

Following removal of the reducing agent, capsomeres quantitatively reassembled into VLPs. Surprisingly, the reassembled VLPs were much more homogenous in particle size than the cesium and sucrose-gradient purified VLP starting material. When the three stages of the disassembly/reassembly reaction were compared by 10-65% linear sucrose gradients, the purified VLP starting material was distributed across the gradient, with many particles migrating to the position expected for intact VLPs (150-160 S), but with the majority of the protein further down the gradient and in the pellet (FIG. 4a). Similarly, when examined in the electron microscope (FIG. 5a), the VLP starting material was seen to be a mixture of different-sized particles, including full size, 50-55 nm diameter VLPs. It is possible that some disruption of VLPs occurred during extraction and purification, as linear sucrose gradient analysis of earlier stages of the purification process indicated a more homogeneous distribution of particle sizes (data not shown).

Upon long-term exposure to high concentrations of reducing agents, the VLPs were disassembled to capsomeres, as described above. Compared to the VLP starting material, the capsomeres migrated at the top of the 10-65% linear sucrose gradients (with little or no L1 detected in the pellet; FIG. 4b), and in the electron microscope appeared as an unbroken field of capsomeres (FIG. 5b).

Reassembly of the capsomeres yielded a homogeneous population of spherical, full-sized VLPs. The reassembled VLPs banded in the middle of the 10-65% linear sucrose gradients, with a predicted sedimentation coefficient of 150.4±4.6 S (n=7), with much less L1 detected either in the pellet or at the bottom of the gradient than was observed with the purified VLP starting material (FIG. 4c). The homogeneity of the reassembled VLPs was even more striking when examined in the electron microscope, as demonstrated in FIGS. 5c,d. Predominantly particles in the range of full-size VLPs were detected, averaging 56.5±7.0 nm (n=15), with very few partially assembled VLPs or smaller complexes apparent. The yields of the reassembly process were also impressive (averaging 83% in terms of total L1 protein from starting material to reassembled VLPs



under optimal disassembly conditions), as essentially all of the capsomeres appeared to reform soluble, filterable, full-size VLPs.

#### Example 4

Comparison of the Ability of Initial Purified HPV-11 VLPs and Reassembled HPV-11 VLPs to Generate Virus-Neutralizing Antibodies.

In order for the reassembled VLPs to function successfully as vaccine candidates, it is essential that they retain the ability to elicit virus-neutralizing antibodies when injected into experimental animals. To test this, polyclonal antisera to both the initial, purified HPV-11 VLPs, and disassembled/reassembled HPV-11 VLPs, were generated in BALB/c mice as described in the Methods section. Each antisera was equally reactive against the corresponding in-immunogen when assayed in an ELISA format (data not shown). More importantly, when tested in the RT-PCR neutralization assay involving infectious HPV-11 virions (Smith et al, *Invest Dermatol.*, 105:1-7(1995)), post-immune reassembled HPV-11 VLP-specific polyclonal antisera exhibited a neutralization titer of 10<sup>-10</sup>-10<sup>-6</sup>, equal to that obtained with the antisera generated against the initial, purified HPV-11 VLPs (FIG. 7). This demonstrates that the reassembled HPV-11 VLPs retain the highly immunogenic, capsid-neutralizing antigenic domain of HPV-11 virions, and have the potential to serve as vaccines for the prevention of genital HPV disease.

#### Example 5

Application of VLP Disassembly and Reassembly During the Purification of HPV VLPs

As discussed above, conventional protein purification methods are not optimized for use with protein complexes the size of VLPs (20,000,000 Da, 55 nm diam. particles). In particular, the sheer size of VLPs dramatically lowers the capacity and utility of most chromatographic resins, as much of the reactive chemistry on the resin is sterically inaccessible to the VLP. However, this difficulty can potentially be avoided by disassembling crude VLPs extracted from cells, purifying the disassembled VLPs using standard methods, and reassembling the VLPs at the desired stage of purity. A second concern with VLP purification is contamination with residual DNA. In earlier work performed with purified HPV-11 VLPs, a certain level of background DNA persists which is not removed by treatment with DNase, suggesting that the DNA is either encapsulated within the VLPs or very intimately associated with them. Disassembly of the VLPs should allow increased removal of contaminating DNA, an important consideration for any biological compound intended for clinical use.

To test this potential, HPV-16<sub>Tr</sub> VLPs were extracted from baculovirus-infected insect cells, and purified by conventional IEC and HIC chromatography as described in the

Methods section, either in the absence of sulphydryl reducing agent (intact VLPs), or in the presence of 4% B-ME (disassembled VLPs). In the latter case, the extracted VLPs were incubated with 4%  $\beta$ ME for >2 hrs. at 4° C. prior to chromatography on IEC and HIC columns, which were also equilibrated in  $\beta$ ME. The final purified products of both purification procedures (i.e., in the presence or absence of sulphydryl reducing agent) were dialyzed against 4x1 L PBS (0.5 M NaCl), and the purity, yield and residual DNA levels were determined. As shown in Table 3, a representative preparation purified in the absence of  $\beta$ ME resulted in HPV-16<sub>Tr</sub> VLPs which were only about 60% pure (in terms of protein contamination) and contained levels of DNA higher than desired for human use. Conversely, three preparations of VLPs purified in the disassembled state were characterized by greater yields, significantly higher protein purity and substantially reduced residual DNA levels. The greater protein purity of VLPs purified in the disassembled state is readily apparent when analyzed by SDS/PAGE, as shown in FIG. 8. The size and homogeneity of the reassembled HPV-16<sub>Tr</sub> VLPs post purification has been more heterogeneous than that observed for reassembly of purified HPV-11 VLPs, but on average have been as homogeneous as HPV-16<sub>Tr</sub> VLPs purified without disassembly, and in some cases have formed uniformly homogeneous, full-sized VLPs, something we have never observed with HPV-16<sub>Tr</sub> VLPs purified without disassembly (data not shown).

There are interesting differences in the effects of prolonged treatment with sulphydryl reducing agents between purified HPV-16<sub>Tr</sub> and HPV-11 VLPs. First, HPV16<sub>Tr</sub> VLPs appear to disassemble quantitatively at lower levels of reducing agent and/or at shorter durations of exposure (data not shown). It is not apparent if this reflects a genuine difference between HPV-16 and HPV-11 VLPs, or if it is due to the C-terminal truncation of the HPV-16<sub>Tr</sub> L1 protein, as in preliminary trials we have observed that proteolytic trimming of the C-terminus of HPV-16 L1 protein also accelerates breakdown of VLPs in the presence of sulphydryl reducing agent. A more interesting feature is that treatment of purified HPV-16<sub>Tr</sub> VLPs with sulphydryl reducing agent appears to generate a mixture of capsomeres, smaller oligomers of the L1 protein and L1 monomer, on the basis of linear 5-20% sucrose gradient analysis of disassembled HPV-16<sub>Tr</sub> VLPs (FIG. 9). However, upon removal of the reducing agent by dialysis, this mix of small, soluble components is able to reassemble into intact VLPs with a yield of 90%, as demonstrated by linear 10-65% sucrose gradient analysis (FIG. 10), and as confirmed by electron microscopic analysis (data not shown). These results demonstrate that VLPs can be disassembled to the level of capsomeres, or even smaller L1 oligomers, and still be competent to reassemble into intact, full-size VLPs, as long as the disassembly conditions generate soluble, correctly-folded L1 proteins.

TABLE 1

Disassembly	Disassembly of HPV-11 L1 VLPs: Effects of reducing agent <sup>a</sup>					
	0.15 M NaCl		0.3 M NaCl		0.5 M NaCl	
Condition	Top	Bottom	Top	Bottom	Top	Bottom
Starting Material	3.8 ± 0.7	96.3 ± 0.8	3.2 ± 1.4	96.8 ± 1.4	4.2 ± 0.3	95.9 ± 0.6
5% $\beta$ ME, 16 hr	87.7 ± 3.2	12.4 ± 3.1	70.9 ± 12	29.1 ± 12	53.2 ± 6.8	46.8 ± 6.8
5 $\beta$ ME, 1 hr	68.1 ± 11	31.9 ± 11	68.0 ± 10	32 ± 10	—	—

TABLE 1-continued

Disassembly of HPV-11 L1 VLPs <sup>a</sup> ; Effects of reducing agents <sup>a</sup>						
Disassembly Condition	0.15 M NaCl		0.3 M NaCl		0.5 M NaCl	
	Top	Bottom	Top	Bottom	Top	Bottom
2% βME, 16 hr	72.1 ± 2.7	27.9 ± 2.7	67.6 ± 2.1	32.3 ± 6.12	—	—
0.5% βME, 16 hr	45.8 ± 1.8	54.2 ± 1.6	28.8 ± 1.6	71.2 ± 1.6	—	—
10 mM DTT, 16 hr	44.5 ± 1.1	55.5 ± 1.1	43.8 ± 2.0	56.2 ± 2.0	—	—
10 mM DTT, 1 hr	9.5 ± 6.4	90.5 ± 6.4	—	—	—	—
10 mM DTT, 5 mM EDTA, 16 hr	55.9 ± 6.2	44.1 ± 6.2	—	—	—	—

<sup>a</sup>VLPs (0.5-1.0 mg/ml protein) were treated as indicated for 16 hours at 4° C., and the distribution of L1 across of 30% sucrose cushion was determined as described in the Methods section. Shown are the means of multiple determinations (n = 3-7) ± the standard deviation.

TABLE 2

Disassembly of HPV-11 L1 VLPs; Effects of chelators and buffers <sup>a</sup>		
Disassembly Condition	Top	Bottom
200 mM EDTA, pH 7.4	4 ± 3	96 ± 3
200 mM EDTA, 10 mM DTT	10 ± 6	90 ± 6
200 mM EGTA, pH 7.4	13 ± 11	87 ± 11
200 mM EGTA, 10 mM DTT	11 ± 6	89 ± 6
200 mM NaHCO <sub>3</sub> , pH 9.6	81 ± 2	19 ± 2
200 mM NaHCO <sub>3</sub> , 10 mM DTT	74 ± 11	26 ± 11
200 mM glycine, pH 9.6	11 ± 1	89 ± 1
200 mM glycine, 10 mM DTT	41 ± 12	59 ± 12

<sup>a</sup>VLPs (0.5-1.0 mg/ml protein) were treated as indicated for 16 hours at 4° C., and the distribution of L1 across of 30% sucrose cushion was determined as described in the Methods section. Shown are the averages of duplicate determinations ± the range.

TABLE 3

Comparison of intact and disassembled HPV-16 <sub>1</sub> VLP purification <sup>a</sup>				
Trial	Scale	Purity	Yield	DNA
-βME	24 g	59%	5.0%	30 ng/100 μg L1
+βME, Run 1	10 g	85%	10.8%	5.3 ng/100 μ L1
+βME, Run 2	10 g	85%	18.4%	0.6 ng/100 μ L1
+βME, Run 3	30 g	81%	6.1%	—

<sup>a</sup>One purification of intact VLPs (-βME) and three purifications of disassembled VLPs (+βME, Runs 1-3) are compared, and were prepared as described in the Methods section. Scale indicates the grams of cell paste used, purity was determined by densitometric analysis of SDS/PAGE of the final product compared to the amount present in the initial cell paste, and DNA was determined by the Threshold method and is reported per 100 μg of L1 protein, the expected maximal individual dose in humans.

## CONCLUSIONS

Thus, the present invention provides precise conditions for the quantitative disassembly and subsequent reassembly of papillomavirus VLPs in vitro. As discussed, earlier attempts at papilloma VLP disassembly were to some extent influenced by work performed upon polyomavirus, a related papovavirus, where it was shown that both reduction of disulfides and chelation of calcium ions were essential for virion disassembly (Brady et al, J. Virol., (1977)). However, it was surprisingly found that the low levels of reducing agent (1-10 mM DTT) optimal for polyomavirus disassembly in the presence of low levels of chelating agents (e.g., 0.5-10 mM EDTA) were only slightly effective at disassem-

bling papilloma VLPs (Table 1, L1 et al, (Id.) (1997)), although partially-trypsinized HPV-11 L1 VLPs were dissociated by the above conditions (L1 et al, (Id.) (1997)). However, Sapp and coworkers demonstrated that capsomeres could be generated from HPV-33 VLPs by treatment with reducing agent alone (20 mM DTT), although the extent of VLP breakdown was not determined (Sapp et al, (Id.) (1995)). In the experiments discussed previously, it was found that when examining disassembly by gradient analysis, it was necessary to test for the presence of L1 protein in the "pellet". In many cases, examination of fractions across the gradient would suggest that good breakdown had been achieved. However, examination of the pellet, even though none was visible, would indicate that a large percentage of the protein was still in the form of variably-sized VLPs or otherwise aggregated, as confirmed by electron microscopic analysis. The development of the 30% sucrose cushion assay allowed us to screen a number of disassembly conditions rapidly and identify those which consistently disassembled the VLPs to smaller, soluble components. It was found that quantitative disassembly to a homogeneous solution of individual capsomeres (for HPV-11 VLPs) or a mixture of capsomeres and correctly-folded smaller L1 oligomers and L1 monomers (HPV 16<sub>1</sub> VLPs) could be consistently achieved by extended treatment of non-aggregated VLPs with high levels of reducing agent in moderate to low ionic strength buffers.

As discussed, the observation that chelation of cations did not materially affect HPV-11 VLP disassembly was surprising as this is in contrast to earlier studies with polyomavirus which indicated that calcium chelation promoted virion disassembly and that added calcium could overcome the effect of chelators (Brady et al, (Id.) (1977)). Similarly, Montross et al, (Id.) (1991), observed that polyomavirus VLPs, which normally assemble only in the nucleus, could form in the cytoplasm following addition of a calcium ionophore, which presumably raised the cytoplasmic calcium concentration to the necessary level. However, calcium is apparently not important to HPV-11 L1 capsid stability. Conversely, treatment with carbonate buffer at alkaline pH did "disassemble" HPV-11 L1 VLPs, similar to results seen with polyomavirus virions (Brady et al, (Id.) (1977)). However, this treatment appears more severe, as VLPs could not be regenerated by dialysis into PB S-0.5 M NaCl following carbonate treatment.

HPV-11 VLP disassembly by carbonate treatment resulted in L1 protein which failed to react with structure-dependent, HPV-11-specific monoclonal antibodies. By contrast, disassembly of HPV-11 L1 VLPs by prolonged reduction resulted in: capsomeres which possessed structure-specific epitopes

found on the surface of both intact HPV-11 L1 VLPs and HPV-11 virions. These results support the idea that only correctly-folded L1 protein retains the ability to reassemble into VLPs.

In order to reassemble full-size-VLPs efficiently in vitro, the results discussed herein indicate that the structural integrity, solubility and homogeneity of the staffing material are significant. Following generation of a such a population of capsomeres (for HPV-11 VLPs) or a mixture of capsomeres and correctly-folded smaller L1 oligomers and L1 monomers (HPV-16<sup>Tr</sup> VLPs) by thiol reduction, reassembly occurs spontaneously upon removal of reducing agent. Reassembly was achieved by removing the sulfhydryl reducing agent, either by column chromatographic methods or by dialysis against a large excess of buffer, yielding a population of reassembled, full-sized VLPs more homogeneous in size than the VLP staffing material. In earlier studies of polyomavirus, Salunke et al, (Id.) (1989) observed that VLP assembly from capsomeres yielded multiple, polymorphic icosahedral assemblies as a function of the assembly conditions (pH, ionic strength, and calcium concentration). Interestingly, the most consistently formed structure was a 24 capsomere icosahedron, as well as a 12 capsomere icosahedron, in addition to the 72 capsomere icosahedron of the viral capsid. The authors noted that disulfide bond formation might aid in polyoma VLP assembly but that it was not essential, as at high ionic strength (2 M ammonium sulfate) variably-sized capsids formed even in the presence of 15 mM 6ME. Similarly, L1 et al, (Id.) (1997), have observed that column-purified HPV-ii capsomeres expressed in *E. coli* have the capacity to form capsid-like structures in 1 M NaCl, again in the presence of 15 mM LIME. However, while high ionic strength conditions apparently favor some degree of capsid formation, it is clear from our studies that at physiological ionic strength, disulfide binds are necessary to hold HPV-11 and HPV-16<sup>Tr</sup> L1 VLPs together.

Even given that the disassembly reactions were typically performed at 4° C. without agitation, it is interesting that maximal disassembly required prolonged exposure to very high levels of reducing agent. As we discussed previously, the most likely explanation is that the stabilizing disulfide

bonds are buried and inaccessible, and that exposure of these bonds to solvent by local structural fluctuations is very infrequent.

The ability to reassemble full-sized VLPs in bulk opens a number of possibilities. As shown in FIG. 7, at high doses reassembled VLPs are capable of eliciting virus-neutralizing antibodies as the purified VLP starting material. Whereas a number of different sized and shaped particles are observed in the nucleus of cells following infection in vivo (Kiselev et al, 1. Mol Biol., 40:155-171, (1969)), presumably only full-sized virus are productively infective. As discussed, the subject reassembled VLPs may potentially exhibit greater stability because of the subject method which provides for more uniform VLP particles. Further, as we discussed above, the reassembly reaction may potentially be further enhanced by varying protein concentration, pH, ionic strength and kinetics, both to optimize reassembly under a greater range of starting conditions. Finally, the subject invention enables the packaging of exogenous compounds within VLPs by performing the reassembly reaction in the presence of a concentrated solution of the selected compound. The subject invention, as discussed above, can be used to generate pseudovirions for use as surrogates for HPV virus types which are not currently available, or as a delivery system for drugs or other targeted compounds.

The disclosure of all patents, publications, including published patent applications, depository accession numbers, and database accession numbers are hereby incorporated by reference to the same extent as if each patent, publication, depository accession number, and database accession number were specifically and individually incorporated by reference.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive, and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All modifications which come within the meaning and range of the lawful equivalency of the claims are to be embraced within that scope.

## SEQUENCE LISTING

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<211> LENGTH: 23  
<212> TYPE: DNA  
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23

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<211> LENGTH: 21  
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<213> ORGANISM: Human Papillomavirus

<400> SEQUENCE: 2

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21

<210> SEQ ID NO 3  
<211> LENGTH: 21

-continued

<212> TYPE: DNA  
 <213> ORGANISM: Human Papillomavirus

<400> SEQUENCE: 3

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21

<210> SEQ ID NO 4  
 <211> LENGTH: 22  
 <212> TYPE: DNA  
 <213> ORGANISM: Human Papillomavirus

<400> SEQUENCE: 4

cagcaatttg tacaggcact ac

22

What is claimed is:

1. A method of producing purified human papillomavirus (HPV) virus-like particles (VLPs) comprising:

purifying a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains said recombinantly expressed HPV L1 protein or truncated version thereof in a form other than a VLP; and

assembling said recombinantly expressed HPV L1 protein or truncated version thereof into purified human papillomavirus virus-like particles (VLPs).

2. The method of claim 1 wherein said human papillomavirus VLPs are selected from the group consisting of HPV-6, HPV-11, HPV-16, HPV-18, HPV-30, HPV-31, HPV-33, HPV-35, HPV-39, HPV-41, HPV-42, HPV-43, HPV-44, HPV-45, HPV-52, HPV-54, HPV-55, HPV-56, HPV-58, HPV-70, and mixtures thereof.

3. The method of claim 2 wherein said human papillomavirus VLP is an HPV-16 VLP.

4. The method of claim 2 wherein said human papillomavirus VLPs are HPV-16 VLPs and HPV-18 VLPs.

5. The method of claim 2 wherein said human papillomavirus VLP is an HPV-11 VLP.

6. The method of claim 1 wherein said reducing agent is a sulfhydryl reducing agent.

7. The method of claim 6 wherein said sulfhydryl reducing agent is  $\beta$ -mercaptoethanol.

8. The method of claim 1 wherein assembly of said HPV L1 protein or truncated version thereof is induced by oxidation or removal of said reducing agent.

9. A method of producing purified human papillomavirus (HPV) virus-like particles (VLPs), comprising:

purifying a recombinantly expressed HPV L1 protein or truncated version thereof in the presence of at least one reducing agent that maintains said recombinantly expressed HPV L1 protein or truncated version thereof in a form other than a VLP; and

assembling said recombinantly expressed HPV L1 protein or truncated version thereof into purified human papillomavirus virus-like particles (VLPs) by removing or oxidizing said at least one reducing agent.

10. The method of claim 9 wherein said human papillomavirus VLPs are selected from the group consisting of HPV-6, HPV-11, HPV-16, HPV-18, HPV-30, HPV-31, HPV-33, HPV-35, HPV-39, HPV-41, HPV-42, HPV-43, HPV-44, HPV-45, HPV-52, HPV-54, HPV-55, HPV-56, HPV-58, HPV-70, and mixtures thereof.

11. The method of claim 10 wherein said human papillomavirus VLP is an HPV-16 VLP.

12. The method of claim 10 wherein said human papillomavirus VLPs are HPV-16 VLPs and HPV-18 VLPs.

13. The method of claim 10 wherein said human papillomavirus VLP is an HPV-11 VLP.

14. The method of claim 9 wherein said reducing agent is a sulfhydryl reducing agent.

15. The method of claim 14 wherein said sulfhydryl reducing agent is  $\beta$ -mercaptoethanol.

\* \* \* \* \*

## EXHIBIT 5



**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING  
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)  
**469201-716**

In re Application of: **McCarthy, et al.**

Application No.: **10/762,928**

Filed: **January 22, 2004**

For: **In Vitro Method for Disassembly/Reassembly of Papillomavirus Virus-Like Particles (VLPs) Homogeneous VLP and Capsomere Compositions Produced by Said Methods; Use Thereof as Vehicle for Improved Purification and Delivery of Active Agents**

The owner, **MedImmune, Inc.**, of **100** percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. **6,962,777** as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:  
expires for failure to pay a maintenance fee;  
is held unenforceable;  
is found invalid by a court of competent jurisdiction;  
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;  
has all claims canceled by a reexamination certificate;  
is reissued; or  
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. **31,778**

Signature

**3/3/06**  
Date

**Raymond J. Lillie**  
Typed or printed name

**973-994-1700**  
Telephone Number

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

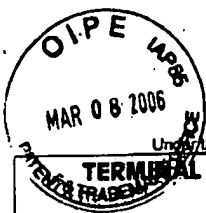
**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

\*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).  
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/26 (09-04)

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**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING  
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)

469201-716

In re Application of: Mc Carthy, et al.

Application No.: 10/762,928

Filed: January 22, 2004

For: In Vitro Method for Disassembly/Reassembly of Papillomavirus Virus-Like Particles (VLPs) Homogeneous VLP and Capsomere Compositions  
Produced by Said Methods; Use Thereof as Vehicle for Improved Purification and Delivery of Active Agents

The owner, MedImmune, Inc., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 6,416,945 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record, Reg. No. 31,778

  
Signature3/3/06

Date

Raymond J. Lillie

Typed or printed name

973-994-1700

Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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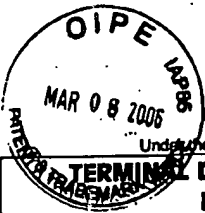
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03/08/2006 EAREGAY1 00000042 10762928

03 FC:1814

130.00 DP



**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING  
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)  
**469201-716**

In re Application of: **McCarthy, et al.**

Application No.: **10/762,928**

Filed: **January 22, 2004**

For: **In Vitro Method for Disassembly/Reassembly of Papillomavirus Virus-Like Particles (VLPs) Homogeneous VLP and Capsomere Compositions Produced by Said Methods; Use Thereof as Vehicle for Improved Purification and Delivery of Active Agents**

The owner, **MedImmune, Inc.**, of **100** percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. **6,261,765** as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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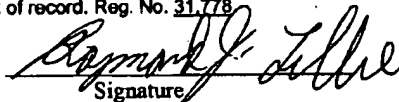
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. **31,778**

  
Signature

**3/3/06**  
Date

**Raymond J. Lillie**

Typed or printed name

**973-994-1700**  
Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

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This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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03/08/2006 ERREGAY1 00000042 10762928

02 FC:1814

130.00 OP



## EXHIBIT 6

AUG-01-2000 13:25

MEDIMMUNE INC

3015274202 P.02



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

OCT 2 1998

1401 Rockville Pike  
Rockville MD 20852-1448

OCT 26 1998

Our Reference: BB-IND 7920

Division of Vaccines and  
Related Products Applications  
Telephone: (301) 827-3070

MedImmune, Inc.  
Attn: Mr. Bogdan Dziurzynski  
35 West Watkins Mill Road  
Gaithersburg, MD 20878

Dear Mr. Dziurzynski:

Reference is made to your Investigational New Drug Application (IND) for "Human Papillomavirus Types 16 and 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda cells) Vaccine with Alum and Monophosphoryl Lipid A Adjuvant." We also refer to your request of September 8, 1998, for Fast Track Drug designation submitted under Section 506 of the Food, Drug, and Cosmetic Act.

We have reviewed your request and concluded that it meets the criteria for Fast Track designation. Therefore, we are designating the investigational "Human Papillomavirus Types 16 and 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda cells) Vaccine with Alum and Monophosphoryl Lipid A Adjuvant" for prevention of cervical cancer as a Fast Track development program.

Under the FDA Modernization Act of 1997, designation as a Fast Track development program for a new drug or biological product means that FDA will take such actions as are appropriate to expedite the development and review of the application for approval of such product. FDA may also evaluate for filing and commence review of portions of an application for approval of a Fast Track product under certain conditions.

FDA is in the process of preparing detailed guidance on the provisions of Section 112 of the FDA Modernization Act of 1997 as required by the Act. Until such time as the guidance is publicly available, please contact our office in order to receive guidance on the development and review of your product and how these provisions will be applied. We look forward to working with you

REGULATORY AFFAIRS  
ARCHIVES

SEP 21 2000

Page 2 - Mr. Bogdan Dziurzynski

to expedite the development and review of this promising proposed use of the product.

If you have any questions, please contact this office at the above telephone number.

Sincerely yours,

*M. Carolyn Hardegree, M.D.*  
*For*

M. Carolyn Hardegree, M.D.  
Director  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research

## EXHIBIT 7

## **Vaccines, Blood & Biologics**

### **Filing Letter - Cervarix, April 9, 2007**

April 9, 2007

GlaxoSmithKline Biologicals  
Attention: Ms. Sharon W. Shapowal  
230 I Renaissance Boulevard  
P.O. Box 61540  
King of Prussia, PA 19406-2772

Dear Ms. Shapowal:

We have received your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

Our Submission Tracking Number (STN): BL 125259/0

Biological Product: Human Papillomavirus Vaccine, AS04 Adjuvant-Adsorbed

Indication: Active immunization to prevent cervical cancer in females 10 years of age and older.

Date of Supplement: March 29, 2007

Date of Receipt: March 29, 2007

First Action Due Date: January 28, 2008

US License: 1617

Please submit all future correspondence, supporting data, or labeling relating to this application in triplicate, citing the above STN number. Send all correspondence to the following address:

We will notify you within 60 days of the receipt date if the application is sufficiently complete to permit a substantive review.

Norman Baylor, Ph.D., HFM-475  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
Suite 200N  
1401 Rockville Pike  
Rockville, MD 20852-1448

We will notify you within 60 days of the receipt date if the application is sufficiently complete to permit a substantive review.

If you have any questions, please contact Ms. Helen Gemignani, Regulatory Project Manager, at (301) 827-3070.

Sincerely yours,

Loris D. McVittie, Ph.D.

Chief

Viral Vaccine Branch

Division of Vaccines and

Related Products Applications

Office of Vaccines

Research and Review

Center for Biologics

Evaluation and Research

# EXHIBIT 8A

Regulatory Affairs  
CARDS  
View Manager Brief Report

Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Initial Investigational New Drug Application: Protocol(s) Included Serial No.: 0000	08-Sep-1998	Yes
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Acknowledgement: Other	26-Oct-1998	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Response to FDA Request/Comment: Clinical, CMC, Nonclinical Serial No.: 0001	18-Dec-1998	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Nonclinical, Nonclinical Serial No.: 0002	20-Jan-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Nonclinical, Study Reports Protocol Amendment: Change in Protocol Serial No.: 0003	01-Feb-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0004	02-Feb-1999	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	14-Apr-1999	Yes



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Communication Type	Seq No	Re Line	Date	Attachments?
General Memorandum: CMC, External Communicatio				
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: CMC, Protocol	20-Apr-1999	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	21-Apr-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0005	22-Apr-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Chemistry Manufacturing and Controls Protocol Amendment: Change in Protocol Serial No.: 0006	03-Jun-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Nonclinical Information Amendment: Clinical Serial No.: 0007	12-Jul-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0008	21-Jul-1999	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	28-Jul-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Other, Administration,	10-Sep-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical: Revised Investigator's Brochure Protocol Amendment: New Protocol Serial No.: 0010	17-Sep-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0011	15-Oct-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Annual Report: Clinical Study Information, Investigational Plan, Outstanding Regulatory Business Serial No.: 0012	24-Nov-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical, Study Reports Serial No.: 0013	02-Dec-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A	07-Dec-1999	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
		General Correspondence: Meeting Request Serial No.: 0014		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: Change in Protocol Serial No.: 0015	16-Dec-1999	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Nonclinical Serial No	16-Dec-1999	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Meeting Agenda or Deta	04-Jan-2000	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: Change in Protocol Serial No.: 0016	11-Jan-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Other, Briefing Docume	11-Jan-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Briefing Document Serial No.: 0017	13-Jan-2000	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	04-Feb-2000	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	04-Feb-2000	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	29-Feb-2000	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Clinical; Sample Case Report Forms and Diary Cards Protocol Amendment: New Investigator, Investigator Add Seri	01-Mar-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Response to FDA Request/Comment: Clinical, Nonclinical Serial No.: 0019	16-Mar-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Meeting Agenda or Deta	24-Mar-2000	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Nonclinical, Nonclinical, Study Reports Serial No.: 0020	17-Apr-2000	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Safety Serial No.: 0021	25-Apr-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Meeting Agenda or Deta	27-Apr-2000	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	27-Apr-2000	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request: CMC, Nonclinical	09-May-2000	Yes
Other Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence, CMC, Stability	16-May-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: Change in Protocol, Clinical Serial No.: 0022	24-May-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Clinical Protocol Synopses Serial No.: 0023	08-Jun-2000	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence	20-Jun-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Clinical, Meeting Request, Protocol Serial No.: 0024	28-Jun-2000	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	03-Jul-2000	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Meeting Request; MedImmune Letter	03-Jul-2000	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	05-Jul-2000	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Meeting Agenda or Details	17-Jul-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical; Revised Investigator's Brochure Protocol Amendment: New Protocol Serial No.: 0025	25-Jul-2000	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	31-Jul-2000	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	31-Jul-2000	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	31-Jul-2000	Yes
Other Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence	01-Aug-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A 15-Day ADR Report: Initial Serial No.: 0026	23-Aug-2000	Yes
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Minutes of Meeting: Minutes of 7/31/2000 Telecon	01-Sep-2000	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Meeting Agenda or Details	01-Sep-2000	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: Change in Protocol Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0027	26-Sep-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical; Revised Investigator Brochure Protocol Amendment: New Investigator, Investigator Add Serial No.: 0028	13-Oct-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Transfer of Ownership Serial No.: 0030	18-Oct-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Transfer of Ownership Serial No.: 0029	18-Oct-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Chemistry Manufacturing and Controls Protocol Amendment: New Investigator Information Amendment: Clinical: Inv	10-Nov-2000	Yes
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Acknowledgement: Transfer of Ownership Genera	13-Nov-2000	Yes



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Communication Type	Seq No	Re Line	Date	Attachments?
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	04-Dec-2000	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Annual Report: Clinical Study Information, Investigational Plan, Outstanding Regulatory Business Serial No.: 0032	08-Dec-2000	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator, Other 1572 Change Protocol Amendment: Change in Protocol; Amendment 2 to HPV-005 Serial No.: 003	12-Dec-2000	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	07-Feb-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator, Investigator Add Protocol Amendment: New Investigator, Other 1572 Change Protocol Amendment: Cha	07-Feb-2001	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	09-Feb-2001	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A	23-Feb-2001	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
		Information Amendment: Nonclinical, Nonclinical, Study Reports Serial No.: 0035		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Response to FDA Request/Comment: Clinical, Protocol Serial No.: 0036	02-Apr-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator, Investigator Add Protocol Amendment: New Investigator, Other 1572 Change Serial No.: 0037	10-Apr-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator, Investigator Add Protocol Amendment: Change in Protocol; Amendment 004 to HPV-003 and Amendment 0	23-Apr-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Response to FDA Request/Comment: CMC Serial No.: 0039	27-Apr-2001	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Meeting Agenda or Details, Status Update	06-Jun-2001	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator, Other 1572 Change Protocol Amendment: New Investigator, Investigator Add	22-Jun-2001	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0040		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: Change in Protocol, Clinical Serial No.: 0041	03-Aug-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator, Investigator Add Protocol Amendment: New Investigator, Other 1572 Change Serial No.: 0042	10-Aug-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Clinical	10-Oct-2001	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Meeting Request: Agency/Sponsor Teleconference	25-Oct-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Briefing Documents Serial No.:	29-Oct-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol; Amendm	31-Oct-2001	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 10025; Influenza Split Virus Trivalent (Type A & B; chicken egg) Vaccine, Inactivated, Intradermal Serial No.: 0002 BBIND 2846; Engerix-B® (Hepatitis B Vaccine (Recombinant)) Serial No.: 0118 BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated)	31-Oct-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Initial Report of Spontaneous Aporion (miscarriage)	13-Nov-2001	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical	13-Nov-2001	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Draft Agenda of Vaccines and Related Biological Products Advisory Committee Meeting dated for November 28, 29, 2001	13-Nov-2001	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Notes for Speakers at VRBPAC Meeting, November 2001	15-Nov-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A 15-Day ADR Report: Initial	19-Nov-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence	20-Nov-2001	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum; Initial Report of Sudden Infant Death Syndrome (Priorix)	30-Nov-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Annual Report	07-Dec-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator, Other 1572 Change Protocol Amendment: Change in Protocol, Clinical Serial No.: 0048	19-Dec-2001	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Minutes of Meeting	14-Jan-2002	Yes
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence Minutes of Meeting	18-Jan-2002	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request	29-Jan-2002	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator, Investig	31-Jan-2002	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator, Investig	26-Feb-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: Other	08-Apr-2002	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator, Other 15	24-May-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol Serial	31-May-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: Change in Protocol, Clinical Serial No.: 0055	20-Jun-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A 15-Day ADR Report: Initial Serial No.: 0056	22-Jul-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical Updated Investigator Brochure	31-Jul-2002	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0057		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Investigator Serial No.: 0058  BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vacc	20-Aug-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical, Statistical Study Protocol 580299/001 (HPV-001) Report Analysis Plan Serial No.: 0059	06-Sep-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle (recombinant L1; Spodoptera frugiperda cells) Vaccine with Alum and Monophosphoryl Lipid A Adjuvant; SB 580299 Protocol Amendment to Protocols MI-CP044, MI-CP055 and MI-CP057	01-Nov-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda cells) Vaccine with Alum and Monophosphoryl Lipid A Adjuvant Updated Investigator Documentation for Study Protocol SB 580299/001(HPV-001) S	04-Nov-2002	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Other, Clinical study protocol question	15-Nov-2002	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A	18-Nov-2002	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
General Memorandum: Clinical				
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence Subject: US Agent (Authorized Official) for Communications Serial No.: 0062	19-Nov-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Annual Report: Adverse Event Summary, Changes to Investigator's Brochure, Clinical Study Information, Foreign Marketing Developments, I	26-Nov-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Correspondence: CMC Serial No.: 0064	03-Dec-2002	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Nonclinical; Reproducti	09-Dec-2002	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Comment/Information Request: CMC, Draft Protocol	08-Jan-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Chemistry Manufacturing and Controls, CMC Serial No.: 0066	10-Jan-2003	Yes



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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Clinical, Meeting Request	13-Jan-2003	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Draft Protocol	16-Jan-2003	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Clinical, Meeting Request	27-Jan-2003	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Other - Request from CBER for teleconference to clarify general clinical questions from new reviewer	04-Feb-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: Change in Protocol, Clinical Information Amendment: Clinical Serial No.: 0067	06-Feb-2003	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Meeting Agenda or Details for the 2/13/2003 Meeting	06-Feb-2003	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Memorandum: Meeting Agenda or Details	25-Mar-2003	Yes

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FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Other - Informal teleconference requested by FDA for clarification of clinical questions	03-Apr-2003	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Response to FDA Request/Comment: Flow Diagrams for the HPV Manufacturing Process	04-Apr-2003	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Response to FDA Request/Comment: Viral Safety of the HPV Pro Vaccine	04-Apr-2003	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: CMC - Inclusion bodies in Sf-9 WCB & request to address at EOP2 meeting	04-Apr-2003	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Meeting Agenda or Details, Other - Sf-9 WCB inclusion bodies (CBER feedback)	15-Apr-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol and Information Amendment: Clinical - Draft Phase 3 clinical study protocols HPV-008 and HPV-009 Request for Feedback Serial	06-Jun-2003	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Other - HPV-008 & -009 concept protocol submission	13-Jun-2003	No

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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Particle Vaccine with Alum and Monophosphoryl Lipid A Additional Copy of Serial No. 0068	19-Jun-2003	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Clinical, Draft Protocol	10-Jul-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical, Study Reports Serial No.: 0069	16-Jul-2003	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Other - CBER request fo informal telecon to discuss Phase 3 concept protocols HPV-008 & -009	22-Jul-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical - Final Clinical Study Report Serial No.: 0070	23-Jul-2003	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Other - CBER telecon to provide GSK with comments on Phase 3 concept protocols HPV-008 & -009	29-Jul-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Information Amendment: Clinical – Final Clinical Study Report MI-CP055	05-Aug-2003	Yes

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		Serial No.: 0071		
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A General Teleconference: Other - Gopa Raychaudhuri replaces Bob Anderson as HPV Regulatory Project Manager	19-Aug-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Protocol Amendment: New Protocol 580299/007 (HPV-007) Serial No.: 0072	19-Aug-2003	Yes
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus-like Particle Vaccine with Alum and Monophosphoryl Lipid A Minutes of 7/29/2003 Teleconference	04-Sep-2003	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Clinical, CMC  STN:	22-Sep-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Formal Meeting Request for PDUFA Products -	24-Sep-2003	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Request	25-Sep-2003	Yes

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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Authorized Official	26-Sep-2003	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	07-Oct-2003	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other - Follow-up disc	15-Oct-2003	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Clinical, Statistical	15-Oct-2003	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Statistical - Re	15-Oct-2003	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	20-Oct-2003	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Other - Parti	24-Oct-2003	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	03-Nov-2003	Yes

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical - Summary of Octo		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Minutes from teleconf	06-Nov-2003	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Briefing Document Inf	06-Nov-2003	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator Documenta	07-Nov-2003	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Annual Report Covering the Period from 9/8/200	19-Nov-2003	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Clinical, Statistical	20-Nov-2003	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other - Proposed discu	04-Dec-2003	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	05-Dec-2003	No

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		General Teleconference: Meeting Agenda or Deta		
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	05-Dec-2003	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Additional US Agent (	05-Dec-2003	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	09-Dec-2003	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	10-Dec-2003	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference - EOP2 meeting details	15-Dec-2003	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Formal Meeting Request for PDUFA Products, Typ	17-Dec-2003	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Summary of 18 December	18-Dec-2003	No

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GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	19-Dec-2003	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	31-Dec-2003	Yes
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes of Dec 5, 2003 Meeting	02-Jan-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes of Type C Meeting Dec 05, 2003 Seria	07-Jan-2004	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical - Draft Informed	14-Jan-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request for Information: G	20-Jan-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Information Package for	20-Jan-2004	Yes



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GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Meeting Agenda or Deta	18-Feb-2004	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other - List of Participan	18-Feb-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical -- Interim	23-Feb-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investigat	24-Feb-2004	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Clinical - CBER feedba	05-Mar-2004	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Summary of End of Feb 18, 2004 Phase II Meeti	11-Mar-2004	Yes
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes of Feb 18, 2004 Meeting	19-Mar-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	22-Mar-2004	Yes

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Final Phase III Protocol		
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Protocol - Call to inf	24-Mar-2004	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendments: Chemistry/Microbio	29-Mar-2004	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Protocol - Telecon to	20-Apr-2004	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	23-Apr-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigators for Stud	03-May-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Final Phase III Protocol 5	18-May-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	28-May-2004	Yes

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		Protocol Amendment: New and Revised Investiga		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator for P	10-Jun-2004	Yes
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Meeting Request	18-Jun-2004	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigators for P	30-Jun-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigators and	30-Aug-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Transfer of Respon	11-Oct-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigators and	13-Oct-2004	Yes

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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0097	16-Nov-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0098	24-Nov-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0099	30-Nov-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Annual Report Covering the Period From Sep 8,	07-Dec-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0102	09-Dec-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Protocol 280299/008 Ame	09-Dec-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	13-Dec-2004	Yes

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		Protocol Amendment: Investigator Revisions		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Invest	17-Dec-2004	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0105	22-Dec-2004	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Other	10-Jan-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Protocol 580299/007, A	11-Jan-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Invest	04-Feb-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0108	09-Feb-2005	Yes

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GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0191 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	10-Feb-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine General Correspondence: Other: Update to list of US Agents and Authorized Officials and Confirmation o	21-Feb-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0112	23-Feb-2005	Yes
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0193 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	23-Feb-2005	Yes
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0194 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	04-Mar-2005	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Safety	08-Mar-2005	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0195 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	09-Mar-2005	Yes

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Safety	16-Mar-2005	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other	23-Mar-2005	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Provided GSK	29-Mar-2005	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Requested Slides	29-Mar-2005	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other	29-Mar-2005	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0197 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	31-Mar-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	01-Apr-2005	Yes

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		Protocol Amendment: New and Revised Invest		
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Draft Protocol: Request fo	05-Apr-2005	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Planned Protocol: HPV-01	06-Apr-2005	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other	06-Apr-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Request for FDA Review of Proposal and Conc	06-Apr-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Invest	08-Apr-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0118	21-Apr-2005	Yes



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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol; Ame	25-Apr-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Protocol 580299/008 A	29-Apr-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0122	05-May-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Other: Investigator Revisions for Protoco	05-May-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Final Draft Protocol H	20-May-2005	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Protocol, Reques	24-May-2005	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Other	25-May-2005	No

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GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0199 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	03-Jun-2005	Yes
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0200 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	07-Jun-2005	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other	10-Jun-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Amendment 001 to Proto	10-Jun-2005	Yes
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Protoco	17-Jun-2005	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clarification	24-Jun-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	24-Jun-2005	Yes

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		Protocol Amendment: New and Revised Invest		
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other	27-Jun-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0128	27-Jun-2005	No
GSK Trip Report		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes From the Jun 28, 2005 Teleconference W	28-Jun-2005	Yes
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical: Pro	28-Jun-2005	Yes
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0202 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	30-Jun-2005	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 BBIND 3200; Havrix® (Hepatitis A Vaccine, Inac	06-Jul-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	06-Jul-2005	No

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		15-Day ADR Report: Initial Serial No.: 0130		
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	06-Jul-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0132	07-Jul-2005	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0203 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	07-Jul-2005	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other	08-Jul-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0134	11-Jul-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0133	11-Jul-2005	No

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FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Safety	15-Jul-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0135	20-Jul-2005	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0204 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	21-Jul-2005	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0208 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	04-Aug-2005	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Nonclinical; Upda	10-Aug-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Serial No.: 0136 BBIND 3200; Havrix® (Hepati	10-Aug-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Safety; Authorized	10-Aug-2005	No

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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Chemistry Manufactur	16-Aug-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol 580299/01	24-Aug-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0141	25-Aug-2005	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0210 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-Sep-2005	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other: Request for GSK	02-Sep-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Addition to Author	08-Sep-2005	Yes

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GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0211 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	09-Sep-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol (HPV)	09-Sep-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised New Investigat	12-Sep-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0147	14-Sep-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0148	26-Sep-2005	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: FDA Is Awaiting the CM	28-Sep-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	29-Sep-2005	No

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		Serial No.: 0149		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical; US Clinica	30-Sep-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0151	04-Oct-2005	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details;	05-Oct-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0152	06-Oct-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0154	13-Oct-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Chemistry Manufactu	13-Oct-2005	No



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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0155	25-Oct-2005	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Request Status Update	04-Nov-2005	No
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: FDA Provided Reco	14-Nov-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Final Protocol HPV-015	14-Nov-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical -- ICSR #M	14-Nov-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0158	17-Nov-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence and Submission of Tr	18-Nov-2005	Yes

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FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: DMF, Protocol: FD	21-Nov-2005	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: DMF, Protocol: HP	21-Nov-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: CMC; Proposal for	22-Nov-2005	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator Docum	22-Nov-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Annual Report Covering the Period From Sep 8,	28-Nov-2005	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Nonclinical:	30-Nov-2005	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 BBIND 9231; Human Rotavirus (strain 89-12; RIX	02-Dec-2005	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0219 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	05-Dec-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Invest	05-Dec-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol; Am	06-Dec-2005	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other: Request Status	08-Dec-2005	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical	13-Dec-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Protocol	14-Dec-2005	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175))	20-Dec-2005	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0221 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0168	20-Dec-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0167	20-Dec-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator and R	20-Dec-2005	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0171	21-Dec-2005	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical; FDA's	29-Dec-2005	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical	29-Dec-2005	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0172	29-Dec-2005	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Requested Clarificatio	12-Jan-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Protocol; Addend	17-Jan-2006	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical; Sample	19-Jan-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Sample I	19-Jan-2006	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Supplementa	23-Jan-2006	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0176	24-Jan-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0175	24-Jan-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical; Sample Informed	25-Jan-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Amendment: Other: Schedule for a Rolling B	30-Jan-2006	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0180	03-Feb-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0179	03-Feb-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0178	03-Feb-2006	No

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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0181	07-Feb-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0184	14-Feb-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0224 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	14-Feb-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Informed Consequence	14-Feb-2006	Yes
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Safety; Discussion	15-Feb-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0226 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	17-Feb-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0225 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	17-Feb-2006	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	20-Feb-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0227 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	23-Feb-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0187	23-Feb-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0228 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	24-Feb-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical ; Two Repo	28-Feb-2006	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0194	01-Mar-2006	No



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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0193	01-Mar-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0229 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Meeting Request; T	01-Mar-2006	Yes
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0230 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	07-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Change in Authori	08-Mar-2006	Yes
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0231 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	10-Mar-2006	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	13-Mar-2006	Yes

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General Memorandum: Meeting Agenda or Details				
GSK Telephone Conversation		BBIND 12107; Fluarix™ (Intramuscular Influenza Split Virus Vaccine, Trivalent, Types A & B) BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	16-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0199	16-Mar-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0232 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	16-Mar-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum; Cervarix Press Release	17-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Invest	17-Mar-2006	Yes
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Investigator Documenta	17-Mar-2006	Yes

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0233 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	23-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0202	23-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0205	27-Mar-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0234 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	27-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0206	28-Mar-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Briefing Document for S	31-Mar-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0237 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	03-Apr-2006	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0236 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	03-Apr-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0238 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	04-Apr-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Plans for Addition	05-Apr-2006	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Efficac	06-Apr-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0212	06-Apr-2006	No
FDA Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Effic	07-Apr-2006	No

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GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Meeting Agenda or Deta	07-Apr-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0239 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	07-Apr-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Discussion of the Imp	11-Apr-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0216	14-Apr-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0215	14-Apr-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0241 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	14-Apr-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0242 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	18-Apr-2006	No

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GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Question on Cellular F	21-Apr-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investi	24-Apr-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol HPV-018 Se	24-Apr-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Attendee List for	28-Apr-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: CMC, Meeting Agenda or Det	28-Apr-2006	No
GSK Trip Report		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Type: Pre-BLA Meeting Minutes	01-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	01-May-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0221		
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0245 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-May-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0247 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	03-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised investigator D	04-May-2006	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details;	08-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0225	10-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0224	10-May-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Protocol 580299/016 (	15-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0230	16-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0229	16-May-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0250 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	16-May-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0249 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	16-May-2006	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference - Tradename, SAS codes,	19-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	22-May-2006	No



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Communication Type	Seq No	Re Line	Date	Attachments?
Protocol Amendment: New and Revised Invest				
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0232	23-May-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum; May 1, 2006 PreBLA Meeting	24-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: May 1, 2006 PreBLA	24-May-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0253 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	24-May-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0252 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	24-May-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0254 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	26-May-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0236	26-May-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	26-May-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	26-May-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	26-May-2006	No
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes of May 1, 2006 Pre-BLA Meeting	31-May-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	31-May-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: CMC; Proposed Manu	31-May-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0255 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	06-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0243	06-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0242	06-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0241	06-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0240	06-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0239	06-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	08-Jun-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
General Correspondence: Additional Authorized				
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0247	09-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0246	09-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Pre-BLA Meeting Min	12-Jun-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0259 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	14-Jun-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0258 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	14-Jun-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0260 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	15-Jun-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0253	15-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0252	15-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0251	15-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0256	16-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0255	16-Jun-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Statistical: Provision	22-Jun-2006	No
FDA Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	26-Jun-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
General Teleconference: Status Update on Fast				
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0258	27-Jun-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0262 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	27-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0262	28-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0261	28-Jun-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0260	28-Jun-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0263 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	28-Jun-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: FDA's Position on Fas	03-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0264	03-Jul-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0264 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	03-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0268	05-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0267	05-Jul-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0266 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	05-Jul-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0265	05-Jul-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Other; Reques	07-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes of Jun 22, 2006 Teleconference Serial	07-Jul-2006	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	08-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0270	10-Jul-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details	11-Jul-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0268 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	11-Jul-2006	No



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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0267 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	11-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investig	11-Jul-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: List of Meeting Participan	12-Jul-2006	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Details;	13-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0274	13-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0277	14-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0276	14-Jul-2006	No

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GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0269 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	14-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0279	18-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0278	18-Jul-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Details Regar	21-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0283	24-Jul-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0272 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	24-Jul-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175))	24-Jul-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0271 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0270 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	24-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Nonclinical (BLA Noncli	31-Jul-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0289	01-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0276 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0275 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0274 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-Aug-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0273 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Protocol (HPV-018)	02-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0277 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	07-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0292	07-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0291	07-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes of Jul 12, 2006 Teleconference Serial	09-Aug-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0281 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	15-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0280 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	15-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0295	15-Aug-2006	No
FDA Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comments Regarding the Apr 24, 2006 Submission	17-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0283 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	18-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0300	22-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0286 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	22-Aug-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0301	23-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0304	28-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0288 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	28-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0287 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	28-Aug-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised In	31-Aug-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0289 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	01-Sep-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0307	01-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigator Do	01-Sep-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0290 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	06-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol, CI	07-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0316	08-Sep-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0293 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	08-Sep-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175))	08-Sep-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0292 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0313	08-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0312	08-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Study Reports	08-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0317	11-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0318	12-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Proposed HPV-008 Revis	12-Sep-2006	No



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Communication Type	Seq No	Re Line	Date	Attachments?
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other; Volume 18 From Seri	14-Sep-2006	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Inclusion of Nonc	15-Sep-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0295 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	18-Sep-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0294 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	18-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0321	18-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0320	18-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	20-Sep-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0324		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0325	25-Sep-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Other, Statistical Re	27-Sep-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigator Do	04-Oct-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0327	06-Oct-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator Document	10-Oct-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0297 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	13-Oct-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Statistical	16-Oct-2006	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Cervarix Addition	18-Oct-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol, Clinic	19-Oct-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Advanced Copy of Slide Pre	24-Oct-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0332	24-Oct-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0298 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	27-Oct-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0336	30-Oct-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0299 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	30-Oct-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigato	30-Oct-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol, Clinic	01-Nov-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0300 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	06-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0338	06-Nov-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0301 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	07-Nov-2006	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	10-Nov-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Request to Sort Ou		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0347	13-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0346	13-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0345	13-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0344	13-Nov-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0304 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	13-Nov-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0303 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	13-Nov-2006	No

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GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0302 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	13-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Addition to Author	17-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Invest	21-Nov-2006	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	22-Nov-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0307 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	27-Nov-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0306 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	27-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	27-Nov-2006	No
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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0353		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0352	27-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0351	27-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Annual Report Covering the Period From Sep 8,	27-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0357	28-Nov-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0356	28-Nov-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0310 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	04-Dec-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0309 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	04-Dec-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0308 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	04-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0366	08-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0365	08-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0364	08-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0363	08-Dec-2006	No



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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol, Clinical, Sa	08-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigat	08-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investigato	12-Dec-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0311 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	13-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0369	14-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0371	18-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0370	18-Dec-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0312 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	19-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0379	21-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0378	21-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0377	21-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0376	21-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0375	21-Dec-2006	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0374	21-Dec-2006	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0373	21-Dec-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0314 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	22-Dec-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0315 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	28-Dec-2006	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0316 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	05-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investi	12-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	17-Jan-2007	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Initial Serial No.: 0385		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0384	17-Jan-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0318 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	19-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator Docume	19-Jan-2007	No
GSK Telephone Conversation		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	25-Jan-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0319 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	29-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0391	29-Jan-2007	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0390	29-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0389	29-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0388	29-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0393	31-Jan-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0394	05-Feb-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0320 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	06-Feb-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175))	07-Feb-2007	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0321 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0400	08-Feb-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0399	08-Feb-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0398	08-Feb-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0397	08-Feb-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investi	09-Feb-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	13-Feb-2007	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0404		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0403	13-Feb-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0402	13-Feb-2007	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Other, Protocol	19-Feb-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0323 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	19-Feb-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0322 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	19-Feb-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0324 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	20-Feb-2007	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator Docum	22-Feb-2007	No
GSK FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other	25-Feb-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol 107682	01-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0412	05-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0411	05-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0410	05-Mar-2007	No
FDA Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Other	06-Mar-2007	No



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GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0415	06-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0414	06-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0413	06-Mar-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0326 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	07-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0417	07-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Investigator Termi	07-Mar-2007	No

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GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical, O	09-Mar-2007	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Other, Meeting	09-Mar-2007	No
FDA FAX/E-mail		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other - BLA Proposal	09-Mar-2007	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other, Protocol, Safety,	09-Mar-2007	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Teleconference: Clinical, Other, Pro	12-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0421	12-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0420	12-Mar-2007	No

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GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0327 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	12-Mar-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0328 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	13-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0423	13-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0422	13-Mar-2007	No
GSK Correspondence		BBIND 3200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0329 BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-M	15-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0426	15-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine	15-Mar-2007	No

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		with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investig		
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0430	22-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0429	22-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0428	22-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical; HPV-009 A	23-Mar-2007	No
GSK Correspondence		BBIND 7920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 0433	26-Mar-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol, Clin	26-Mar-2007	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	30-Mar-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0330 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	30-Mar-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investiga	04-Apr-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0331 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	09-Apr-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0438	10-Apr-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	18-Apr-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle	18-Apr-2007	No

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		(recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Inves		
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical, P	25-Apr-2007	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Proto	25-Apr-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Inve	25-Apr-2007	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Other	30-Apr-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0442	01-May-2007	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Protocol - May	03-May-2007	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0443	16-May-2007	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Stati	17-May-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigator	18-May-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Other Additional In	18-May-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	23-May-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	23-May-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	24-May-2007	No

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		Serial No.: 0448		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	05-Jun-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	06-Jun-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0451	06-Jun-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0450	06-Jun-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0332 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	08-Jun-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	08-Jun-2007	No



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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	08-Jun-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0336 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	12-Jun-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0335 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	12-Jun-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0334 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	12-Jun-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0333 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	12-Jun-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0337 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	15-Jun-2007	No
GSK Telephone		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	03-Jul-2007	No
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Conversation		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0462	10-Jul-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	10-Jul-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Inves	17-Jul-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	20-Jul-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Safety	20-Jul-2007	No
FDA FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 Comment/Information Request: Clinical, Protocol, Safety - Pregnancy Outcomes and MPL Adverse Events	26-Jul-2007	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera fr		
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0340 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	26-Jul-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0339 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	26-Jul-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0338 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	26-Jul-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0471	31-Jul-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0342 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	31-Jul-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0341 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	31-Jul-2007	No

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FDA Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 BBIND 005505; Herpes Simplex Type 2 Virus (R	02-Aug-2007	No
FDA Correspondence		BBIND 005505; Herpes Simplex Type 2 Virus (Recombinant gD2t; CHO cells) BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl	03-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Additional Author	08-Aug-2007	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 BBIND 005505; Herpes Simplex Type 2 Virus (R	09-Aug-2007	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 BBIND 005505; Herpes Simplex Type 2 Virus (R	09-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical Serial	13-Aug-2007	No
GSK FAX/E-mail		BBIND 005505; Herpes Simplex Type 2 Virus (Recombinant gD2t; CHO cells) BBIND 010514; RTS,S/AS02A malaria vaccine [RTS,S recombinant antigen adjuvanted to AS02A] BBIND 012100; Human Papillomavirus Type 16, Type 18, Type 31 and Type 45 Virus Like Particl	16-Aug-2007	No

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FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 BBIND 005505; Herpes Simplex Type 2 Virus (R	16-Aug-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0345 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	16-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Clinical IB and IC	17-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	22-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	23-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Safety:	27-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	29-Aug-2007	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0479		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0480	30-Aug-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	05-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	05-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol, Clinical	07-Sep-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0346 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	10-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol 10893	10-Sep-2007	No

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FDA FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 Comment/Information Request: Clinical, CMC, Other - VRBPAC; IC/IB Language  BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia	11-Sep-2007	No
GSK FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 General Memorandum: Clinical, Other - VRBPAC and Request for Technical Presentation  BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Tri	11-Sep-2007	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical, C	12-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	12-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0487	17-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0488	19-Sep-2007	No

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FDA FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 Comment/Information Request: Clinical - Unblinded Treatment Assignments and Clinical Narratives  BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugi	20-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	21-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0490	24-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	25-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	25-Sep-2007	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 BBIND 012100; Human Papillomavirus Type 16,	26-Sep-2007	No



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Communication Type	Seq No	Re Line	Date	Attachments?
FDA FAX/E-mail		BBIND 012100; Human Papillomavirus Type 16, Type 18, Type 31 and Type 45 Virus Like Particle (recombinant L1; Trichoplusia ni cells) Vaccine with Alum and 3-O-Deacylated Monophosphoryl Lipid A Adjuvant BBIND 007920; Human Papillomavirus Type 16 and Type	26-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Response to Inform	28-Sep-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0494	01-Oct-2007	No
GSK FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 Response to FDA Request/Comment: Statistical - Detailed Description of Test Statistics used for Testing the Homogeneity of Odds Ratios  BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Part	04-Oct-2007	No
FDA FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 Comment/Information Request: Statistical - Detailed Description of Test Statistics used for Testing the Homogeneity of Odds Ratios  BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle	04-Oct-2007	No
GSK FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 Response to FDA Request/Comment: Statistical - GSK Response to Homogeneity Testing Comment  BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	04-Oct-2007	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Clinical GSK Not	05-Oct-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	10-Oct-2007	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other - ACIP Presentatio	16-Oct-2007	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Other - ACIP Pr	16-Oct-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	23-Oct-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and revised Inves	25-Oct-2007	No
GSK Correspondence		BBIND 003200: Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0348	26-Oct-2007	No

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		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and		
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0347 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	26-Oct-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	26-Oct-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 04	26-Oct-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol, Clinical,	30-Oct-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol, Clin	01-Nov-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0505	06-Nov-2007	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0506	08-Nov-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Additional Authorize	09-Nov-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0508	15-Nov-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0509	26-Nov-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	04-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0510	04-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	05-Dec-2007	No

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		Protocol Amendment: New and Revised Invest		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Annual Report Covering Period Sep 8, 2006 Th	05-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0515	07-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator Serial	07-Dec-2007	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0352 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	11-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol (HPV-	12-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	13-Dec-2007	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	14-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	14-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Statistical	19-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0524	20-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	20-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	20-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	27-Dec-2007	No

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		Serial No.: 05		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0525	27-Dec-2007	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	17-Jan-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	18-Jan-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	21-Jan-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	21-Jan-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	22-Jan-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0532	24-Jan-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0531	24-Jan-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	30-Jan-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Invest	30-Jan-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol, Clin	01-Feb-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0537	06-Feb-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	06-Feb-2008	No



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		Serial No.: 05		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	07-Feb-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0353 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	12-Feb-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	18-Feb-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	20-Feb-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Stati	25-Feb-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Stati	25-Feb-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	25-Feb-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0354 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	25-Feb-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other - Courtesy Submiss	26-Feb-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Other - Courtesy Submiss	26-Feb-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0544	26-Feb-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0545	29-Feb-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigator	05-Mar-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0547	06-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0550	10-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0549	10-Mar-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0355 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	10-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	14-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0552	14-Mar-2008	No

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GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0356 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	14-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	21-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	21-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0554	21-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0557	24-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	26-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	26-Mar-2008	No

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		15-Day ADR Report: Initial Serial No.: 0558		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	28-Mar-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	01-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	03-Apr-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	03-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment HPV-010:	04-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0565	14-Apr-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0564	14-Apr-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Other, Protoco	15-Apr-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Other - Upcomin	15-Apr-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Proto	16-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol HPV-0	18-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Inve	18-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	21-Apr-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	21-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0568	21-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Statistical	21-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	25-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	25-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	25-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	25-Apr-2008	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0578	29-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0577	29-Apr-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	01-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0581	07-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0580	07-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	09-May-2008	No



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		Serial No.: 0584		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	09-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	09-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	13-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0585	13-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Inves	16-May-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Efficacy, Othe	18-May-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0588	19-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	20-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	20-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	20-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0589	20-May-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0357 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	21-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	21-May-2008	No

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General Correspondence: Proposal to Revise t				
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	27-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	28-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 05	30-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0597	30-May-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	05-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	05-Jun-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0599	05-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	10-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0602	10-Jun-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Safet	12-Jun-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical, E	12-Jun-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Effic	12-Jun-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Efficacy, Prot	12-Jun-2008	No

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FDA Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Safet	12-Jun-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Effic	12-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigator	12-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comments (HPV-023 an	13-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	16-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	16-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	16-Jun-2008	No

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		Serial No.: 06		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0608	16-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0607	16-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0606	16-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0615	18-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0614	18-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	18-Jun-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	18-Jun-2008	No
FDA FAX/E-mail		STN: BL 125259; Cervarix US License No. 0000 Comment/Information Request General Memorandum: Meeting Agenda or Details  BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells)	19-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	23-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	23-Jun-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Effic	26-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0619	26-Jun-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	26-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0625	27-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	27-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	27-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	27-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	27-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	27-Jun-2008	No



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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Change of the Primar	30-Jun-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0627	03-Jul-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0358 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	08-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0633	08-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0632	08-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	08-Jul-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	08-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	08-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	08-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	16-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0636	16-Jul-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0359 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	16-Jul-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	17-Jul-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0361 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	29-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	29-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0640	29-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0639	29-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	30-Jul-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	01-Aug-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Initial Serial No.: 0644		
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Proto	06-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	06-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	06-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	06-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0647	06-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0646	06-Aug-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0645	06-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0651	13-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Follow-up on the Dis	14-Aug-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0363 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	20-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	21-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0655	21-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	21-Aug-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Initial Serial No.: 0654		
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical, S	26-Aug-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Details for the	27-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator and Rev	27-Aug-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	28-Aug-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	28-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	29-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	29-Aug-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Follow-up Serial No.: 06		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0660	29-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0659	29-Aug-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0658	29-Aug-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Protocol, S	04-Sep-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Protocol, Stati	04-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	09-Sep-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	10-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	10-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0666	10-Sep-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0365 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	10-Sep-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0364 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	10-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	15-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	15-Sep-2008	No



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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Follow-up Serial No.: 06		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0670	15-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0669	15-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Statistical	18-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0676	19-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0675	19-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical: HPV-016 Ann	19-Sep-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment Dated June 12	22-Sep-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	23-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0680	24-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	24-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0678	24-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	26-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0682	26-Sep-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0681	26-Sep-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	26-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0685	30-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0684	30-Sep-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, HPV-010 Stu	02-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0692	03-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	03-Oct-2008	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0691		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0689	03-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0688	03-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	03-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Comments of August 6, 2008:	03-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	10-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0699	10-Oct-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0698	10-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	10-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0696	10-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	10-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0694	10-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 06	10-Oct-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical: HPV-007 Mon	17-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0706	20-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0705	20-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	20-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	20-Oct-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0366 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	20-Oct-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Additional Safe	22-Oct-2008	No

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GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Request for	23-Oct-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Efficacy, Stati	24-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol 111955 (HPV)	24-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0711	27-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0710	27-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0709	27-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	27-Oct-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0708		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	28-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0719	30-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0718	30-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	30-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0716	30-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0715	30-Oct-2008	No



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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0714	30-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0713	30-Oct-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Submission	31-Oct-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	04-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	05-Nov-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	06-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0722	06-Nov-2008	No

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GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	10-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigator Doc	10-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0737	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0736	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0735	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	11-Nov-2008	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0733		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0732	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0730	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0729	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0728	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	11-Nov-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0727		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0726	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0725	11-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0724	11-Nov-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Other	12-Nov-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Clinical, Other - Reques	12-Nov-2008	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Safety - Oct 20	12-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	12-Nov-2008	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07		
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Safety - Oc	13-Nov-2008	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0747	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0746	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Nov-2008	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0743	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0742	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0740	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0739	17-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0755	18-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	18-Nov-2008	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0753	18-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0752	18-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	18-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	18-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0749	18-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	18-Nov-2008	No

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		Serial No.: 0748		
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0368 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	20-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0762	25-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0761	25-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0760	25-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0759	25-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0758	25-Nov-2008	No



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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	25-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	26-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0765	26-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0764	26-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0763	26-Nov-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Initial Investigator Doc	01-Dec-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	03-Dec-2008	No

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		7-Day Safety Report		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0769	05-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0768	05-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Annual Report Period Covering Sep 8, 2007 th	08-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0780	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0779	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0778	09-Dec-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0777	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0775	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0774	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	09-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	09-Dec-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Follow-up Serial No.: 07		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol 10893	10-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol HPV-0	11-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol HPV-0	11-Dec-2008	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0370 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	12-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0785	15-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0786	16-Dec-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol 10482	16-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0793	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	17-Dec-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0791		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 07	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0789	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical: HPV-16 and	17-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical: HPV-009 Exp	18-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	19-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	19-Dec-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0799	19-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0798	19-Dec-2008	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	22-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0805	23-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0804	23-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	23-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	23-Dec-2008	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0802		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	30-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0812	30-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0811	30-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0810	30-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0809	30-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0808	30-Dec-2008	No



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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0807	30-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0806	30-Dec-2008	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	05-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0815	05-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	05-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0818	07-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0818	07-Jan-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0821	08-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0820	08-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0819	08-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigators for Pr	09-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence: Additional Authorize	13-Jan-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Safety - Safety	14-Jan-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	15-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	16-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0829	16-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0828	16-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	16-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	16-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	16-Jan-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Initial Serial No.: 0825		
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	21-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	23-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0840	27-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0839	27-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	27-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0837	27-Jan-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0836	27-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0835	27-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	27-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0833	27-Jan-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0832	27-Jan-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Request - Reques	04-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	04-Feb-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Follow-up Serial No.: 08		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0845	04-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0844	04-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0843	04-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0842	04-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0841	04-Feb-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Other - Tentati	05-Feb-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0849	05-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	05-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0847	05-Feb-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Safety - Safety	06-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0855	06-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0854	06-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	06-Feb-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Initial Serial No.: 0853		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	06-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	06-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	06-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0858	09-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	09-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator and Rev	09-Feb-2009	No



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GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	10-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Revised Investigators S	11-Feb-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	12-Feb-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	12-Feb-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	13-Feb-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	13-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	17-Feb-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	17-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0863	17-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0862	17-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0861	17-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0860	17-Feb-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	18-Feb-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	24-Feb-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		General Memorandum: Meeting Agenda or Detail		
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	24-Feb-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	24-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0868	24-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0867	24-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0866	24-Feb-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	27-Feb-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	27-Feb-2009	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail		
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0372 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	27-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	27-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0871	27-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0870	27-Feb-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	27-Feb-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Meeting Agenda or Detail	03-Mar-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	03-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0875	04-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investig	05-Mar-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Clinical, E	06-Mar-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: Clinical, Effic	06-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	06-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0877	06-Mar-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, 109179 (HPV)	06-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	11-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0883	12-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0882	12-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	12-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0885	13-Mar-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	13-Mar-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	13-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	23-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0892	23-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0891	23-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0890	23-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	23-Mar-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 08		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	23-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	23-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	23-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	25-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0895	26-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 08	27-Mar-2009	No



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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0897	27-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0896	27-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0899	30-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	31-Mar-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	02-Apr-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	06-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	06-Apr-2009	No

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		15-Day ADR Report: Initial Serial No.: 0905		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0904	06-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	06-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investig	06-Apr-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: GSK HPV Slides for April	08-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0906	09-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	10-Apr-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0908	10-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0907	10-Apr-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	15-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	17-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	17-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0912	17-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	17-Apr-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0911		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Minutes of March 9, 2009 Meeting and Minutes	17-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	20-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0915	20-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0917	21-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	27-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	27-Apr-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0922	27-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0921	27-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0920	27-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0919	27-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol 112024 (HPV)	27-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0925	29-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	30-Apr-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0928		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	30-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	30-Apr-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	04-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Safety Ser	06-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investig	08-May-2009	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0373 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	11-May-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	11-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	11-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	11-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0933	11-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0932	11-May-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: HPV-044 RAP Com	13-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	13-May-2009	No

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		Serial No.: 09		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0946	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0945	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0944	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0943	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0942	18-May-2009	No



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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0941	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0940	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0939	18-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	19-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	19-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0948	19-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	21-May-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0968	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0967	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0966	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	21-May-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 0965		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0964	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0963	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0962	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0961	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0960	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0959	21-May-2009	No

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Communication Type	Seq No.	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0958	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0957	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0956	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0955	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0954	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0953	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0953	21-May-2009	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0952		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0951	21-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0976	22-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0975	22-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	22-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0973	22-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial	22-May-2009	No

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		Serial No.: 0972		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0986	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0985	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0984	28-May-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0983	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0982	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0981	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0980	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0979	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0978	28-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0978	28-May-2009	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Comments: HPV-044 Draft RAP		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical, Study Repor	29-May-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	02-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 09	02-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0995	02-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0994	02-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0993	02-Jun-2009	No



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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0992	02-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0991	02-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	03-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0999	03-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 0998	03-Jun-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment, Request to	04-Jun-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	04-Jun-2009	No

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Comment/Information Request: Request to Batc				
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	04-Jun-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Follow-up with CBER on R	05-Jun-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Follow-up with CBER on	05-Jun-2009	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0375 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	05-Jun-2009	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0374 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	05-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	05-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	05-Jun-2009	No

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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1003		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1002	05-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1001	05-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1010	09-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1009	09-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1008	09-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	09-Jun-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 10		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1017	12-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	12-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	12-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	12-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1013	12-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1012	12-Jun-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1011	12-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1019	18-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1018	18-Jun-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	18-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1024	22-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1023	22-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	22-Jun-2009	No

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		15-Day ADR Report: Initial Serial No.: 1022		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1021	22-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1020	22-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1027	25-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1026	25-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1025	25-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	26-Jun-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	26-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1030	26-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1029	26-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1028	26-Jun-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Cervarix Proper (generic)	29-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	29-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	29-Jun-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	29-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1033	29-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Correspondence:HPV-009 Follow-up to	29-Jun-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	02-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	02-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	07-Jul-2009	No



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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1045	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1044	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1043	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1042	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1041	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1040	07-Jul-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1048	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1047	07-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1058	09-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1057	09-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	09-Jul-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Initial Serial No.: 1056		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	09-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1053	09-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1052	09-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	09-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New and Revised Investig	09-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1059	13-Jul-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	16-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	16-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	16-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	16-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1062	16-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1061	16-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	16-Jul-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1060		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1070	21-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	21-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	21-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	21-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical: 107682 (HPV)	23-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	27-Jul-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1078	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1077	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1076	27-Jul-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1075	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1074	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1073	27-Jul-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	27-Jul-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1072	27-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Response to	29-Jul-2009	No

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GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0377 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	30-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	30-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	30-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1085	30-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1084	30-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1091	31-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	31-Jul-2009	No



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		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	31-Jul-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	04-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1095	06-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	06-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	06-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	07-Aug-2009	No

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		Serial No.: 11		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 10	07-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1098	07-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1097	07-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1096	07-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	13-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	13-Aug-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	13-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1102	13-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1101	13-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1107	14-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1106	14-Aug-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	20-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	21-Aug-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Follow-up Serial No.: 11		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	21-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	21-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1111	21-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1110	21-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1109	21-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1108	21-Aug-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1115	24-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1118	25-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	25-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	25-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	28-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	28-Aug-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	28-Aug-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical - Revised St	03-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1131	04-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1130	04-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1129	04-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	04-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	04-Sep-2009	No

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	Serial No.: 11		
GSK Telephone Conversation	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	04-Sep-2009	No
GSK Correspondence	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	04-Sep-2009	No
GSK Correspondence	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	04-Sep-2009	No
GSK Correspondence	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	04-Sep-2009	No
GSK Correspondence	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1123	04-Sep-2009	No
GSK Correspondence	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1135	10-Sep-2009	No

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GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	10-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	10-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	10-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	14-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1138	15-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	15-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	17-Sep-2009	No



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		15-Day ADR Report: Initial Serial No.: 1140		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1139	17-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1144	21-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1143	21-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	21-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1141	21-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	24-Sep-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1146	24-Sep-2009	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0381 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	24-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1148	25-Sep-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	30-Sep-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	01-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1152	01-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda	01-Oct-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1151		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1150	01-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol: HPV-	01-Oct-2009	No
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	06-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	06-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1155	06-Oct-2009	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0382 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	06-Oct-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Telephone Conversation		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 7-Day Safety Report	08-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1162	09-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1161	09-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1160	09-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1159	09-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1158	09-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	09-Oct-2009	No

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CARDS  
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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Follow-up Serial No.: 11		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1164	13-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1163	13-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	16-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1168	16-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1167	16-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1166	16-Oct-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator and Rev	16-Oct-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Follow-up on SAP Submiss	19-Oct-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Comment/Information Request: HPV-009 Statist	23-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1171	23-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	23-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	27-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up	27-Oct-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
		Serial No.: 11		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	27-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	27-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1173	27-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1172	27-Oct-2009	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0383 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	29-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	29-Oct-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	29-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	29-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	30-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	30-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Chemistry Manufacturi	30-Oct-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	02-Nov-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299	06-Nov-2009	No



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Communication Type	Seq No	Re Line	Date	Attachments?
		15-Day ADR Report: Follow-up Serial No.: 11		
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	06-Nov-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	12-Nov-2009	No
GSK Correspondence		BBIND 003200; Havrix® (Hepatitis A Vaccine, Inactivated (Strain HM175)) Serial No.: 0384 BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and	12-Nov-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: HPV-009 Rev	13-Nov-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Investigator Document	17-Nov-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: Change in Protocol, Clin	19-Nov-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Protocol Amendment: New Protocol; Postmarket	20-Nov-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Initial Serial No.: 1194	25-Nov-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Response to FDA Request/Comment: Safety, Po	03-Dec-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Response to Dec. 4 switc	04-Dec-2009	No
GSK FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Switch to eCTD format	04-Dec-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	04-Dec-2009	No
GSK Correspondence		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Serial No.: 11	04-Dec-2009	No

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Communication Type	Seq No	Re Line	Date	Attachments?
GSK Correspondence	1198	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Sequence No: 1	08-Dec-2009	No
FDA FAX/E-mail		BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 General Memorandum: Status Update, Postmarke	09-Dec-2009	No
GSK Correspondence	1199	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 Information Amendment: Clinical Sequence No	09-Dec-2009	No
GSK Correspondence	1200	BBIND 007920; Human Papillomavirus Type 16 and Type 18 Virus Like Particle (recombinant L1; Spodoptera frugiperda and Trichoplusia ni cells) Vaccine with Alum and 3D-Monophosphoryl Lipid A Adjuvant, SB 580299 15-Day ADR Report: Follow-up Sequence No: 1	11-Dec-2009	No

## EXHIBIT 8B

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Jul-2006	BLA 125259		Cervarix General Memorandum Other	810f9b75

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Teresa Ward	Food and Drug Administration Ms. Laurie Norwood	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Mar-2007	BLA 125259		Cervarix General Memorandum Advertising/Promotion	80fbc20c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Vincent I. Ahonkhai, M.D.	Food and Drug Administration Dr. Norman Baylor, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Advertising/Promotion SUBTYPES: Advertising/Promotion

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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11/10/2009 10:33:45 AM

Page: 1 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

29-Mar-2007	BLA 125259; BLA 125259	Seq#: 0000	Cervarix User Fee N/A Original Submission N/A	80fa1cf1
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	USER FEE SUBTYPES: N/A SUBTYPES: N/A SUBTYPES: N/A SUBTYPES: N/A SUBINDEXING: Protocol: 103514 Report: 103514 Protocol: 104479 Report: 104479 Protocol: 104772 Report: 104772 Protocol: 104798 Report: 104798 Protocol: 104820 Report: 104820 Protocol: 104896/013 Report: 104896/013 Protocol: 104951 Report: 104951 Protocol: 105926 Report: 105926 Protocol: 106001 Report: 106001 Protocol: 107682 Report: 107682 Protocol: 580299/001 Report: 580299/001 Protocol: 580299/002 Report: 580299/002 Protocol: 580299/003 Report: 580299/003 Protocol: 580299/004 Report: 580299/004 Protocol: 580299/005 Report: 580299/005 Protocol: 580299/007 Report: 580299/007 Protocol: 580299/008
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 580299/012

Report: 580299/012

DESCRIPTION:DESCRIPTORS:

ECTD: ESG

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

No

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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09-Apr-2007	BLA 125259		Cervarix Acknowledgement NDA # Assigned	80fd781a
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Loris D. McVittie, Ph.D.	GlaxoSmithKline Ms. Sharon Shapowal	Correspondence	ACKNOWLEDGEMENT SUBTYPES: NDA # Assigned SUBTYPES: NDA # Assigned

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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25-Apr-2007	BLA 125259		Cervarix Comment/Information Request Clinical	81038d7d
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST COMMENT/INFORMATION REQUEST

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

SUBTYPES: Protocol; Clinical

SUBTYPES: Protocol; Clinical

Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-May-2007	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	8101f525

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-May-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Clinical Efficacy	810392b0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM

11/10/2009 10:33:46 AM



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Ms. Sharon Shapowal  
Administration  
Dr. Helen Sullivan

SUBTYPES: Clinical; Efficacy  
SUBTYPES: Clinical; Efficacy  
Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-May-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Efficacy	8103ad70

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Efficacy SUBTYPES: Clinical; Efficacy Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-May-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Other	8103acd5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical
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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-May-2007	BLA 125259; BLA 125259; BLA 125259		Cervarix Topic Clinical Efficacy Other	8100fd93

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Trip Report	TOPIC SUBTYPES: Other; Clinical; Efficacy SUBTYPES: Other; Clinical; Efficacy Protocol: 104479 Protocol: 104820 Protocol: 109890 Protocol: 580299/001 Protocol: 580299/007 Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

11-May-2007	BLA 125259; BLA 125259; BLA 125259	Cervarix General Teleconference Clinical CMC Safety	8100c1da
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: CMC; Clinical; Safety SUBTYPES: CMC; Clinical; Safety Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-May-2007	BLA 125259	Cervarix General Correspondence N/A		80ffa039

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Vincent I. Ahonkhai, M.D.	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

21-May-2007 BLA 125259

Cervarix  
Comment/Information Request  
Other

80ff3b24

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other Protocol: 580299/008

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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22-May-2007 BLA 125259

Cervarix  
Comment/Information Request  
Other

80ff37ba

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other Protocol: 580299/008

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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22-May-2007 BLA 125259

Cervarix

80ff376e

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Response to FDA Request/Comment  
Other

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Sharon Shapowal	Administration		SUBTYPES: Other
	Dr. Helen Sullivan		SUBTYPES: Other
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-May-2007	BLA 125259		Cervarix	810177a8
			Response to FDA Request/Comment	
			Clinical	

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Sharon Shapowal	Administration		SUBTYPES: Clinical
	Dr. Helen Sullivan		SUBTYPES: Clinical
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-May-2007	BLA 125259		Cervarix	81017824
			Comment/Information Request	

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Clinical

FROM: TO: COMMUNICATION: DOCTYPE & SUBTYPE:  
Food and Drug Administration Dr. Helen Sullivan GlaxoSmithKline Ms. Sharon Shapowal FAX/E-mail COMMENT/INFORMATION REQUEST  
SUBTYPES: Clinical  
SUBTYPES: Clinical  
Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-May-2007	BLA 125259		Cervarix Acknowledgement Other	81004ac4

FROM: TO: COMMUNICATION: DOCTYPE & SUBTYPE:  
Food and Drug Administration Mr. Paul Richman GlaxoSmithKline Ms. Sharon Shapowal Correspondence ACKNOWLEDGEMENT  
SUBTYPES: Other  
SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-May-2007	BLA 125259	Seq#: 0001	Cervarix Seq #: 0001 Amendment to Pending Application Other	80ff5506

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Ms. Sharon Shapowal	Administration		SUBTYPES: Other
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Other

DESCRIPTION:

GSK provided responses to FDA regarding communications dated May 7, 2007 and May 16, 2007.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Jun-2007	BLA 125259	Seq#: 0002	Cervarix Seq #: 0002 Amendment to Pending Application Other	80ff4e8b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Ms. Sharon Shapowal	Administration		SUBTYPES: Other
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Other
			Protocol: 580299/008

DESCRIPTION:

GSK submitted additional information and audit details for site 4923 as requested in the 4/30/2007 FDA letter.

DESCRIPTORS:

ECTD; ESG

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Jun-2007	BLA 125259	Seq#: 0003	Cervarix Seq #: 0003 Amendment to Pending Application Other	80ffa97

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Ms. Sharon Shapowal	Administration		SUBTYPES: Other
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

ESG: ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Jun-2007	BLA 125259		Cervarix Comment/Information Request CMC	81014d06

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Rebecca Olin	GlaxoSmithKline Ms. Linda S. Kramer	Telephone Conversation	COMMENT/INFORMATION REQUEST SUBTYPES: CMC SUBTYPES: CMC SUBINDEXING: Lot Number: AC20B084A Lot Number: AC20B084B Lot Number: AC20B086A Lot Number: AC20B086B Lot Number: AHPVA005B Lot Number: AHPVA005C Lot Number: AHPVA006A Lot Number: AHPVA006B Lot Number: AHPVA007A Lot Number: AHPVA007B

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Jun-2007	BLA 125259		Cervarix Comment/Information Request CMC	81010d60

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Chiang Syin	GlaxoSmithKline Ms. Linda S. Kramer	Telephone Conversation	COMMENT/INFORMATION REQUEST SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Jun-2007	BLA 125259		Cervarix Response to FDA Request/Comment CMC	810335f5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC SUBTYPES: CMC SUBINDEXING: Lot Number: AC20B084A Lot Number: AC20B084B Lot Number: AC20B086A Lot Number: AC20B086B Lot Number: AHPVA005B Lot Number: AHPVA005C Lot Number: AHPVA006A Lot Number: AHPVA006B Lot Number: AHPVA007A Lot Number: AHPVA007B

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Jun-2007	BLA 125259		Cervarix Response to FDA Request/Comment CMC	81013318

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Linda S. Kramer	Food and Drug Administration Ms. Rebecca Olin	Telephone Conversation	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Jun-2007	BLA 125259; BLA 125259	Seq#: 0004	Cervarix Seq #: 0004 Amendment to Pending Application Statistical Response to FDA Request/Comment Statistical	81015102

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Statistical SUBTYPES: Statistical SUBTYPES: Statistical SUBTYPES: Statistical

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Jun-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment CMC Other	810d548f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Gopa Raychaudhuri	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Jun-2007	BLA 125259	Seq#: 0005	Cervarix Seq #: 0005 Response to FDA Request/Comment CMC	81019fce

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Linda S. Kramer	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Jul-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	81077d5d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Jul-2007	BLA 125259; BLA 125259		Cervarix General Memorandum CMC Meeting Request	8104cecb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Gopa Raychaudhuri	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Meeting Request SUBTYPES: CMC; Meeting Request

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Jul-2007	BLA 125259		Cervarix Comment/Information Request CMC	8103ee59

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Gopa Raychaudhuri	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Jul-2007	BLA 125259; BLA 125259		Cervarix General Memorandum CMC Other	810c3504

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Gopa Raychaudhuri	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Jul-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	810c36ee

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Gopa Raychaudhuri	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Jul-2007	BLA 125259		Cervarix Comment/Information Request Clinical	81077d4b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 103514 Protocol: 104479 Protocol: 104772 Protocol: 107682 Protocol: 109890

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Jul-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	810c373f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Gopa Raychaudhuri	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Jul-2007	BLA 125259		Cervarix Comment/Information Request CMC	8104cfff

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Gopa Raychaudhuri	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Jul-2007	BLA 125259		Cervarix Comment/Information Request Clinical	8109b41f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Jul-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8109b45b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 102115/HPV TETRA 051 Protocol: 103514 Protocol: 104772 Protocol: 104820 Protocol: 580299/001



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 580299/007

Protocol: 580299/008

Protocol: 580299/009

Protocol: 580299/012

Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Jul-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical CMC	8103eccc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Shahabuddin Muhammad	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC; Clinical SUBTYPES: CMC; Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Jul-2007	BLA 125259		Cervarix General Memorandum CMC	810c4b87

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Jul-2007	BLA 125259	Cervarix Comment/Information Request Clinical		8109b4d1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 103514 Protocol: 104772 Protocol: 104820 Protocol: 580299/007 Protocol: 580299/008 Protocol: 580299/012 Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11/10/2009 10:33:46 AM				

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

20-Jul-2007 BLA 125259

Cervarix

8109cb11

Response to FDA Request/Comment  
Clinical

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Clinical
	Dr. Helen Sullivan		SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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23-Jul-2007 BLA 125259

Cervarix

810d4832

Comment/Information Request  
CMC

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Ms. Weining L. Hu		SUBTYPES: CMC
Dr. Muhammad			SUBTYPES: CMC
Shahabuddin, Ph.D.			

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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23-Jul-2007 BLA 125259;

Cervarix

8109b417

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

BLA 125259

Comment/Information Request  
Clinical  
Safety

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 103514 Protocol: 580299/008 Protocol: 580299/012

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COMMENT/INFORMATION REQUEST

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Jul-2007	BLA 125259	Seq#: 0006	Cervarix Seq #: 0006 Amendment to Pending Application CMC	8103eecf

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC SUBTYPES: CMC

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DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jul-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8109b54b

FROM: TO: COMMUNICATION: DOCTYPE & SUBTYPE:  
Food and Drug Administration Dr. Helen Sullivan  
GlaxoSmithKline Mr. Matthew Whitman  
FAX/E-mail  
COMMENT/INFORMATION REQUEST  
SUBTYPES: Clinical; Safety  
SUBTYPES: Clinical; Safety  
Protocol: 580299/009

COMMENT/INFORMATION REQUEST

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jul-2007	BLA 125259	Seq#: 0007	Cervarix Seq #: 0007 Response to FDA Request/Comment N/A	81044bef

FROM: TO: COMMUNICATION: DOCTYPE & SUBTYPE:  
GlaxoSmithKline Mr. Matthew Whitman  
Food and Drug Administration Dr. Norman Baylor, Ph.D.  
Correspondence  
RESPONSE TO FDA REQUEST/COMMENT  
SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:

GSK submitted an amendment to the BLA to provide a response to the first of the 3 CBER requests from the Jul 6, 2007 e-mail

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Yes

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Aug-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8109b596

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Aug-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8109b5c0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Yes

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Aug-2007	BLA 125259		Cervarix	810524db

Comment/Information Request  
Safety

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	Telephone Conversation	COMMENT/INFORMATION REQUEST
			COMMENT/INFORMATION REQUEST
			SUBTYPES: Safety
			SUBTYPES: Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Aug-2007	BLA 125259	Seq#: 0008	Cervarix Seq #: 0008	8104cd8c

Response to FDA Request/Comment  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	Correspondence	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A
			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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03-Aug-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8109b5f3
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 104820

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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07-Aug-2007	BLA 125259		Cervarix Comment/Information Request CMC	81056c57
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	Correspondence	COMMENT/INFORMATION REQUEST SUBTYPES: CMC SUBTYPES: CMC

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Aug-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	81058969

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 104772 Protocol: 104820 Protocol: 580299/012

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Aug-2007	BLA 125259; BLA 125259	Seq#: 0009	Cervarix Seq #: 0009 Response to FDA Request/Comment Clinical Safety	81054cb8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Yes

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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12-Aug-2007	BLA 125259; BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety Statistical	8105cce7
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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Food and Drug Administration Dr. Gopa Raychaudhuri	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Statistical; Safety SUBTYPES: Clinical; Statistical; Safety
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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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14-Aug-2007	BLA 125259		Cervarix General Teleconference Advisory Committee Meeting	8105d65c
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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Food and Drug Administration Dr. Norman Baylor, Ph.D.	GlaxoSmithKline Mr. Matthew Whitman	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: Advisory Committee Meeting SUBTYPES: Advisory Committee Meeting
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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Aug-2007	BLA 125259	Seq#: 0010	Cervarix Seq #: 0010 Response to FDA Request/Comment N/A	81057644

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:

GSK provided unblinded treatment assignments and available clinical narratives for selected subjects in study HPV-009 as a result fo the FDA e-mail communication containing sent by Ms. Helen Gemignani on August 1, 2007.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Aug-2007	BLA 125259	Seq#: 0011	Cervarix Seq #: 0011 Response to FDA Request/Comment Safety	81060716

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Safety SUBTYPES: Safety

DESCRIPTION:

GSK provided comments to the e-mail communication containing FDA comments sent by Ms. Helen Gemignani on August 1, 2007.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Aug-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8109b65e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2007	BLA 125259	Seq#: 0012	Cervarix Seq #: 0012 Response to FDA Request/Comment Clinical	8106e95c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Vincent I. Ahonkhai, M.D.	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2007	BLA 125259; BLA 125259		Cervarix General Memorandum CMC Other	8108b298

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Other SUBTYPES: CMC; Other SUBINDEXING: Lot Number: AHPVA005B

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2007	BLA 125259		Cervarix General Memorandum N/A	8106f7b4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. David A. Donohue	Food and Drug Administration Dr. Michael Fauntleroy	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

This involves doc id 8106e95c.

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2007	BLA 125259		Cervarix General Memorandum N/A	81076ce7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Michael Fauntleroy	GlaxoSmithKline Mr. David A. Donohue	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Meeting Request Other	810b929

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mr. Gang Wang	GlaxoSmithKline Ms. Teresa Ward	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Meeting Request SUBTYPES: Other; Meeting Request

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

28-Aug-2007	BLA 125259; BLA 125259	Cervarix Response to FDA Request/Comment CMC Other	81071485
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Teresa Ward	Food and Drug Administration Dr. Chiang Syin	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Aug-2007	BLA 125259; BLA 125259	Cervarix Comment/Information Request CMC Other		810bf9e5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Chiang Syin	GlaxoSmithKline Ms. Teresa Ward	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Aug-2007	BLA 125259	Cervarix		810bf9be

11/10/2009 10:33:46 AM

Page: 35 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

General Memorandum  
Meeting Agenda or Details

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Teresa Ward	Administration		SUBTYPES: Meeting Agenda or Details
	Mr. Gang Wang		SUBTYPES: Meeting Agenda or Details

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Aug-2007	BLA 125259		Cervarix	8107882f
			General Memorandum	
			N/A	

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. David A. Donohue	Administration		SUBTYPES: N/A
	Dr. Michael Fauntleroy		SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Aug-2007	BLA 125259		Cervarix	810742c2
			Comment/Information Request	
			Other	

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mr. Gang Wang	GlaxoSmithKline Ms. Teresa Ward	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Aug-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	81074134

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 103514 Protocol: 104772 Protocol: 104820 Protocol: 580299/001 Protocol: 580299/008 Protocol: 580299/012 Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Aug-2007	BLA 125259		Cervarix Response to FDA Request/Comment Other	810737d4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. David A. Donohue	Food and Drug Administration Dr. Michael Fauntleroy	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Aug-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment CMC Other	810747c5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Teresa Ward	Food and Drug Administration Ms. Rebecca Olin	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

30-Aug-2007 BLA 125259

Cervarix  
General Memorandum  
Other

810c0051

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. David A. Donohue	Administration		SUBTYPES: Other
	Mr. Andre McCollough		SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

31-Aug-2007 BLA 125259

Cervarix  
Comment/Information Request  
Nonclinical

81077d39

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: Nonclinical
Mrs. Helen Sullivan			SUBTYPES: Nonclinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

31-Aug-2007 BLA 125259

Cervarix  
Comment/Information Request  
Other

81077d70

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Sep-2007	BLA 125259		Cervarix Comment/Information Request Statistical	8107aa48

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Statistical SUBTYPES: Statistical

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Sep-2007	BLA 125259		Cervarix Comment/Information Request Other	8107f350

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Food and Drug Administration Dr. Michael Fauntleroy	GlaxoSmithKline Mr. David A. Donohue	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other
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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Sep-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	810932f8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 104820 Protocol: 580299/001 Protocol: 580299/007 Protocol: 580299/008 Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Sep-2007	BLA 125259		Cervarix Comment/Information Request	8109331b

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

CMC

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC SUBTYPES: CMC Protocol: 107682

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Sep-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Advisory Committee Meeting Other	810b3b40

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Christine Walsh, R.N.	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Advisory Committee Meeting SUBTYPES: Other; Advisory Committee Meeting

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Sep-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Advisory Committee Meeting	810d5b3f

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Other

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Other; Advisory Committee Meeting
	Ms. Christine Walsh, R.N.		SUBTYPES: Other; Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Sep-2007	BLA 125259	Seq#: 0013	Cervarix Seq #: 0013 General Correspondence N/A	81072a71

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:

GSK provided Page 2 of the annotated individual subject data (Table 1) of the August 27, 2007 submission which contained a corrupted file.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Clinical Other	810cf8ce

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

<b>FROM:</b>	<b>TO:</b>	<b>COMMUNICATION:</b>	<b>DOCTYPE &amp; SUBTYPE:</b>
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Other; Clinical
	Dr. Helen Sullivan		SUBTYPES: Other; Clinical

GENERAL MEMORANDUM

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2007	BLA 125259;		Cervarix	810c920
	BLA 125259;		Comment/Information Request	
	BLA 125259		Clinical	
			CMC	
			Other	

<b>FROM:</b>	<b>TO:</b>	<b>COMMUNICATION:</b>	<b>DOCTYPE &amp; SUBTYPE:</b>
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Ms. Sharon Shapowal		SUBTYPES: CMC; Other; Clinical
Mrs. Helen Sullivan			SUBTYPES: CMC; Other; Clinical

COMMENT/INFORMATION REQUEST

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Sep-2007	BLA 125259;		Cervarix	81088016

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Page: 44 of 299



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

BLA 125259;  
BLA 125259Response to FDA Request/Comment  
Clinical  
CMC  
Other

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT

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RESPONSE TO FDA REQUEST/COMMENT  
SUBTYPES: CMC; Other; Clinical  
SUBTYPES: CMC; Other; Clinical

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Sep-2007	BLA 125259	Seq#: 0014	Cervarix Seq #: 0014 Amendment to Pending Application CMC	81083fa9

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC SUBTYPES: CMC

---

DESCRIPTION:

GSK submitted complete responses to questions one through six of the FDA communication received via e-mail on August 7, 2007.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

13-Sep-2007	BLA 125259; BLA 125259; BLA 125259	Cervarix Comment/Information Request Clinical CMC Other	81089ccb
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other; Clinical SUBTYPES: CMC; Other; Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Sep-2007	BLA 125259	Cervarix Comment/Information Request Clinical		810932c3

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 580299/009  COMMENT/INFORMATION REQUEST

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Sep-2007	BLA 125259	Seq#: 0015	Cervarix Seq #: 0015 Response to FDA Request/Comment Clinical	8108af25

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:

ESG: ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Sep-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment CMC Other	810d49de

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC: Other SUBTYPES: CMC: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Sep-2007	BLA 125259		Cervarix Comment/Information Request Clinical	8109b288

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 108933

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Sep-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	810c39d2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Sep-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment CMC Other	810d4a7f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC: Other SUBTYPES: CMC: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Sep-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	810c4c19

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	GlaxoSmithKline Ms. Weining L. Hu	Telephone Conversation	COMMENT/INFORMATION REQUEST SUBTYPES: CMC: Other SUBTYPES: CMC: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Sep-2007	BLA 125259; BLA 125259	Seq#: 0016	Cervarix Seq #: 0016 Amendment to Pending Application Safety Response to FDA Request/Comment N/A	810918e7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Dr. Vincent I. Ahonkhai,	Administration		SUBTYPES: Safety
M.D.	Dr. Norman Baylor, Ph.D.		SUBTYPES: Safety
			RESPONSE TO FDA REQUEST/COMMENT
			SUBTYPES: N/A
			SUBTYPES: N/A

**DESCRIPTION:**

GSK submitted the Level 3 and Level 4 analyses (Module 5.3.5.3). This submission concludes the commitment to the Agency for meta-analysis of relevant data and represents a complete response to the July 10th safety analysis request.

**DESCRIPTORS:**

ESG; ECTD

**ELECTRONIC MEDIA: MEDIA INFORMATION:**

Yes

**QC COMPLETED: DATE REFERENCED:**

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Oct-2007	BLA 125259		Cervarix Comment/Information Request CMC	810a157b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: CMC
Dr. Helen Sullivan			SUBTYPES: CMC

**DESCRIPTION:****DESCRIPTORS:**

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2007	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	81114790

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Edward M. Yubas, Ph.D.	Food and Drug Administration Mrs. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2007	BLA 125259; BLA 125259		Cervarix General Memorandum CMC Other	810c4e0c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2007	BLA 125259	Seq#: 0017	Cervarix Seq #: 0017 Response to FDA Request/Comment N/A	81099380

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

GSK provided 45 clinical narratives for non-serious adverse events from the total of 66 narratives as requested in the July 18 e-mail, and submitted a complete response to the preclinical request of August 31, 2007:

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2007	BLA 125259		Cervarix Comment/Information Request Clinical	810a587e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Yes

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	810a598d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Oct-2007	BLA 125259		Cervarix Comment/Information Request Statistical	810a9a97

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Statistical SUBTYPES: Statistical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Oct-2007	BLA 125259; BLA 125259		Cervarix General Memorandum CMC Other	810d4cbf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Oct-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Other	81120c52

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Dr. Edward M. Yuhas, Ph.D.	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Oct-2007	BLA 125259		Cervarix Response to FDA Request/Comment Statistical	810cefbc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Statistical SUBTYPES: Statistical

RESPONSE TO FDA REQUEST/COMMENT

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Oct-2007	BLA 125259		Cervarix Comment/Information Request Statistical	810ceff1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Statistical SUBTYPES: Statistical

COMMENT/INFORMATION REQUEST

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Oct-2007	BLA 125259		Cervarix Response to FDA Request/Comment Statistical	810cf051

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Statistical SUBTYPES: Statistical  RESPONSE TO FDA REQUEST/COMMENT

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Oct-2007	BLA 125259		Cervarix General Memorandum Other	810cf00f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Oct-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	810d4d01

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2007	BLA 125259		Cervarix Comment/Information Request Other	810adfe6

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2007	BLA 125259; BLA 125259		Cervarix General Memorandum CMC Other	810c4e4e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Other SUBTYPES: CMC; Other SUBINDEXING: Lot Number: AHPVA018A Lot Number: AHPVA019A Lot Number: AHPVA024A Lot Number: AP16CPA035 Lot Number: AP16CPA036 Lot Number: AP16CPA037 Lot Number: AP18CPA029 Lot Number: AP18CPA030 Lot Number: AP18CPA031

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2007	BLA 125259		Cervarix Comment/Information Request Other	810ac1a1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Oct-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	810d5808

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Oct-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Meeting Agenda or Details Meeting Request	810d576d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Request; Meeting Agenda or Details SUBTYPES: Meeting Request; Meeting Agenda or Details

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Oct-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	810d57e5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Oct-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	810b1171

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Oct-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	810b1116

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Oct-2007	BLA 125259	Seq#: 0018	Cervarix Seq #: 0018 Response to FDA Request/Comment Clinical	810acb89

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Oct-2007	BLA 125259		Cervarix Comment/Information Request Clinical	810b43a1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Oct-2007	BLA 125259		Cervarix Comment/Information Request Clinical	810b6e2d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 208141/005 (HSV-007) Protocol: 208141/016 Protocol: 208141/017 Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Oct-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	810da06c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Oct-2007	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	810d9c27

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 208141/005 (HSV-007) Protocol: 208141/016 Protocol: 208141/017 Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Oct-2007	BLA 125259		Cervarix Comment/Information Request Clinical	810b6de7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Oct-2007	BLA 125259		Cervarix Comment/Information Request Other	810b8186

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST  COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Oct-2007	BLA 125259	Seq#: 0019	Cervarix Seq #: 0019 General Correspondence Other	810b0cd1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Teresa Ward	Food and Drug Administration Ms. Mary Malarkey	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:

GSK provided responses to the observations listed on the Form FDA 483 dated September 21, 2007

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Oct-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment CMC Other	810d4fd5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

11/10/2009 10:33:46 AM

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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16-Oct-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	810c4e9b
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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16-Oct-2007	BLA 125259		Cervarix General Memorandum Other	81110bc0
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	FAX/E-mail	GENERAL MEMORANDUM  GENERAL MEMORANDUM SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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18-Oct-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Advisory Committee Meeting Other	810dalce
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Other; Advisory Committee Meeting
	Dr. Helen Sullivan		SUBTYPES: Other; Advisory Committee Meeting

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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18-Oct-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	810bf6ed
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Meeting Agenda or Details
	Dr. Helen Sullivan		SUBTYPES: Meeting Agenda or Details

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Oct-2007	BLA 125259; BLA 125259; BLA 125259		Cervarix Comment/Information Request Efficacy Other Safety	810ca1ca

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Norman Baylor, Ph.D.	GlaxoSmithKline Dr. Vincent I. Abonkhai, M.D.	Telephone Conversation	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Safety; Efficacy SUBTYPES: Other; Safety; Efficacy

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Oct-2007	BLA 125259		Cervarix General Teleconference CMC	810c4ef8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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19-Oct-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Advisory Committee Meeting Other	810da21c
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Advisory Committee Meeting SUBTYPES: Other; Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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19-Oct-2007	BLA 125259	Seq#: 0020	Cervarix Seq #: 0020 Amendment to Pending Application CMC	810bbde3
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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:

GSK amended the e-CTD for the BLA with complete responses to questions communicated in FDA e-mails received on October 1 and September 7.

DESCRIPTORS:

ESG: ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Oct-2007	BLA 125259		Cervarix Comment/Information Request Other	810dbb94

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Oct-2007	BLA 125259		Cervarix General Memorandum Other	810c0909

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

24-Oct-2007 BLA 125259

Cervarix

810c3864

General Teleconference  
Other

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Ms. Robin Levis	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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24-Oct-2007 BLA 125259

Cervarix

810cd91f

Comment/Information Request  
Clinical

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical

Protocol: 100409  
Protocol: 104888  
Protocol: 106068  
Protocol: 107509  
Protocol: 249553/004  
Protocol: 269814/004  
Protocol: 269814/005  
Protocol: 2885-001  
Protocol: 2885-003  
Protocol: 2885-006  
Protocol: 2885-008  
Protocol: 2885-009  
Protocol: 2885-010  
Protocol: 2885-011  
Protocol: 5023-001  
Protocol: 722461/001

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: M00026/016

Protocol: SWOG9035

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Oct-2007	BLA 125259		Cervarix General Memorandum CMC	810c4fad

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Muhammad Shahabuddin, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Oct-2007	BLA 125259	Seq#: 0021	Cervarix Seq #: 0021 Response to FDA Request/Comment Clinical	810c2048

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

ESG: ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Oct-2007	BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix General Teleconference Advisory Committee Meeting Clinical Other Safety	810ca389

FROM:TO:COMMUNICATION:DOCTYPE & SUBTYPE:

GlaxoSmithKline

Food and Drug

Telephone Conversation

GENERAL TELECONFERENCE

Dr. Vincent I. Ahonkhai,  
M.D.Administration  
Dr. Norman Baylor, Ph.D.

SUBTYPES: Other; Clinical; Safety; Advisory Committee Meeting

SUBTYPES: Other; Clinical; Safety; Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Oct-2007	BLA 125259; BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Advisory Committee Meeting Efficacy Safety	810ca2ac

FROM:TO:COMMUNICATION:DOCTYPE & SUBTYPE:

11/10/2009 10:33:47 AM

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

GlaxoSmithKline	Food and Drug	Telephone Conversation	RESPONSE TO FDA REQUEST/COMMENT
Dr. Vincent I. Ahonkhai,	Administration		SUBTYPES: Safety; Advisory Committee Meeting; Efficacy
M.D.	Dr. Norman Baylor, Ph.D.		SUBTYPES: Safety; Advisory Committee Meeting; Efficacy

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Nov-2007	BLA 125259	Seq#: 0022	Cervarix Seq #: 0022 Response to FDA Request/Comment Clinical	810ba951

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Clinical
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:

ESG: ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Nov-2007	BLA 125259		Cervarix Comment/Information Request Other	810d4734

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Ms. Sharon Shapowal		SUBTYPES: Other
Dr. Helen Sullivan			SUBTYPES: Other

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Nov-2007	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	810df48f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 208141/017

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Nov-2007	BLA 125259; BLA 125259	Seq#: 0023	Cervarix Seq #: 0023 Amendment to Pending Application CMC Labeling	810d178d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC; Labeling SUBTYPES: CMC; Labeling

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:

GSK amended the pending BLA to provide updated immediate container and carton labeling, in addition to potency data previously provided in the October 25th e-mail in addition.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Nov-2007	BLA 125259		Cervarix General Memorandum CMC	810d8a84

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Nov-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Other	810db89b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Nov-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	81117c9a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Nov-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Other	81118249

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Nov-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Other	81117d5d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Nov-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Other	81117d11

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Nov-2007	BLA 125259	Seq#: 0024	Cervarix Seq #: 0024 Response to FDA Request/Comment N/A	810da239

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:

GSK amended the BLA to provide a partial response received from Ms. Helen Gemignani on August 21, 2007 regarding safety outcomes/pharmacovigilance.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Nov-2007	BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Clinical Meeting Request Other	810ec9aa

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Other; Meeting Request; Clinical
	Dr. Helen Sullivan		SUBTYPES: Other; Meeting Request; Clinical

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Nov-2007	BLA 125259	Seq#: 0025	Cervarix Seq #: 0025 Amendment to Pending Application CMC	810e25bb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:

GSK Biologicals completed the QC check of the CMC sections. For ease of review, the inaccuracies or typographical errors identified are tabulated and submitted in Module 1.11.1 "Quality Information Amendment" of the pending BLA.

DESCRIPTORS:

ESG

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Nov-2007	BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Clinical CMC Labeling	81118450

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Clinical; Labeling SUBTYPES: CMC; Clinical; Labeling

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Nov-2007	BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical CMC Labeling Other	81118490

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other; Clinical; Labeling SUBTYPES: CMC; Other; Clinical; Labeling

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Nov-2007	BLA 125259		Cervarix General Memorandum Other	810ec996

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Dec-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Other	8111d97a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Dec-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Other	8111d131

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Dec-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Clinical Other	810f3b63

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Dec-2007	BLA 125259; BLA 125259		Cervarix Comment/Information Request Other Safety	810f9b43

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Safety SUBTYPES: Other; Safety

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Dec-2007	BLA 125259; BLA 125259		Cervarix General Memorandum Other Safety	810f9b21

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Safety SUBTYPES: Other; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Dec-2007	BLA 125259		Cervarix Comment/Information Request Safety	8111da17

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Safety SUBTYPES: Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Dec-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	8111213

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Dec-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	811124a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Dec-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	8111785

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Robin Levis	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Dec-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	8111739a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Dec-2007	BLA 125259;		Cervarix	810fc912

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

BLA 125259

General Memorandum  
Meeting Agenda or Details  
Other

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Meeting Agenda or Details SUBTYPES: Other; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Dec-2007	BLA 125259		Cervarix Response to FDA Request/Comment Other	810fe01b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Ms. Robin Levis	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Dec-2007	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	810fdm09

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Dec-2007	BLA 125259; BLA 125259		Cervarix General Memorandum CMC Meeting Agenda or Details	8111f28c

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: CMC; Meeting Agenda or Details SUBTYPES: CMC; Meeting Agenda or Details

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Dec-2007	BLA 125259		Cervarix Comment/Information Request Safety	810fcbec

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Safety SUBTYPES: Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Dec-2007	BLA 125259	Seq#: 0026	Cervarix Seq #: 0026 Response to FDA Request/Comment N/A	810fcb25

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

GSK amended the BLA to provide a further response to questions received on Aug 21, 2007, specifically Questions 1 and 3a and 3d. This completes the response to the August 21 questions.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Dec-2007	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Safety	811688ae

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Sharon Shapowal	Administration		SUBTYPES: Clinical; Safety
	Dr. Helen Sullivan		SUBTYPES: Clinical; Safety
			Protocol: 100409
			Protocol: 104888
			Protocol: 106068
			Protocol: 107509
			Protocol: 249553/004
			Protocol: 269814/004
			Protocol: 269814/005
			Protocol: 2885-001
			Protocol: 2885-003
			Protocol: 2885-006
			Protocol: 2885-008
			Protocol: 2885-009
			Protocol: 2885-010
			Protocol: 2885-011
			Protocol: 5023-001
			Protocol: 732461/002
			Protocol: M00026/016
			Protocol: SWOG0016
			Protocol: SWOG0025

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Dec-2007	BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix Complete Response Letter Clinical CMC Safety Statistical	8124e96a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Loris D. McVittie,	GlaxoSmithKline Ms. Sharon Shapowal	Correspondence	COMPLETE RESPONSE LETTER SUBTYPES: CMC; Clinical; Statistical; Safety SUBTYPES: CMC; Clinical; Statistical; Safety

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Ph.D.

Protocol: 103514  
Protocol: 104772  
Protocol: 104820  
Protocol: 108933  
Protocol: 580299/001  
Protocol: 580299/007  
Protocol: 580299/008  
Protocol: 580299/009  
Protocol: 580299/012  
Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Dec-2007	BLA 125259; BLA 125259	Cervarix General Teleconference Efficacy Safety		8110aa4d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Clare Kahn, Ph.D.	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: Safety; Efficacy SUBTYPES: Safety; Efficacy Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11/10/2009 10:33:47 AM				

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

20-Dec-2007 BLA 125259 Seq#: 0027 Cervarix Seq #: 0027  
Intent to File Amendment  
N/A

8110485b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	INTENT TO FILE AMENDMENT
Ms. Sharon Shapowal	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Dec-2007	BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Clinical Efficacy Other Safety	81110a9e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Other; Clinical; Safety; Efficacy
	Dr. Helen Sullivan		SUBTYPES: Other; Clinical; Safety; Efficacy

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

31-Dec-2007 BLA 125259;  
BLA 125259Cervarix  
Response to FDA Request/Comment  
Clinical  
Other

8111d0de

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Other; Clinical
	Dr. Helen Sullivan		SUBTYPES: Other; Clinical

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Jan-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	81120276

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Ms. Sharon Shapowal		SUBTYPES: Meeting Agenda or Details
Mrs. Helen Sullivan			SUBTYPES: Meeting Agenda or Details

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Jan-2008	BLA 125259; BLA 125259;		Cervarix General Memorandum	81110a35

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

BLA 125259

Clinical  
Meeting Agenda or Details  
Safety

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Clinical; Safety; Meeting Agenda or Details
	Dr. Helen Sullivan		SUBTYPES: Clinical; Safety; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Jan-2008	BLA 125259		Cervarix General Memorandum Meeting Request	8112021b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Meeting Request
	Dr. Helen Sullivan		SUBTYPES: Meeting Request

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Jan-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	81122658

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Jan-2008	BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Meeting Agenda or Details Other Safety	811171e1

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Safety; Meeting Agenda or Details SUBTYPES: Other; Safety; Meeting Agenda or Details

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Jan-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	811226ca

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Meeting Agenda or Details
	Dr. Helen Sullivan		SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Jan-2008	BLA 125259		Cervarix General Memorandum Other	81117621

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Ms. Sharon Shapowal		SUBTYPES: Other
Dr. Helen Sullivan			SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Jan-2008	BLA 125259		Cervarix General Memorandum Other	8111a948

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Ms. Donna Boyce  
Dr. Joseph J. Temenak

SUBTYPES: Other  
SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Jan-2008	BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix General Teleconference Clinical Efficacy Safety Statistical	8113076f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: Clinical; Statistical; Safety; Efficacy SUBTYPES: Clinical; Statistical; Safety; Efficacy

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Jan-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	8112f0bf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Matthew Whitman  
Mrs. Helen Sullivan

SUBTYPES: Meeting Agenda or Details  
SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jan-2008	BLA 125259; BLA 125259		Cervarix General Memorandum Meeting Agenda or Details Safety	8112f0ee

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Safety; Meeting Agenda or Details SUBTYPES: Safety; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jan-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8112e7e2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Dr. Helen Sullivan

SUBTYPES: Clinical; Safety  
Protocol: 104772  
Protocol: 580299/009  
Protocol: 580299/012DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Jan-2008	BLA 125259	Cervarix General Memorandum Meeting Agenda or Details		8112e204

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Feb-2008	BLA 125259; BLA 125259	Cervarix Comment/Information Request Clinical Safety		8113ef80

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Ms. Sharon Shapowal  
Dr. Helen Sullivan

SUBTYPES: Clinical; Safety  
SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Feb-2008	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Safety	8113e9e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Feb-2008	BLA 125259	Seq#: 0028	Cervarix Seq #: 0028 Response to Not Approvable Letter Nonclinical	8113a954

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO NOT APPROVABLE LETTER SUBTYPES: Nonclinical SUBTYPES: Nonclinical



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Feb-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	81173b5a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Feb-2008	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Safety	811470d0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Feb-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request Other Safety	81146f1e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Safety SUBTYPES: Other; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Feb-2008	BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Advisory Committee Meeting Other Safety	81146f40

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Safety; Advisory Committee Meeting SUBTYPES: Other; Safety; Advisory Committee Meeting

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Feb-2008	BLA 125259		Cervarix Comment/Information Request Other	81146e01

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Feb-2008	BLA 125259		Cervarix Response to FDA Request/Comment Other	81146e37

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Feb-2008	BLA 125259		Cervarix Comment/Information Request Other	81146e6f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Feb-2008	BLA 125259		Cervarix Response to FDA Request/Comment Other	81146efb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Feb-2008	BLA 125259	Seq#: 0029	Cervarix Seq #: 0029 Amendment to Pending Application Clinical	811448e4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:

GSK provided a second partial response to the December 14th CR letter. Specifically, responses to Questions 4 through 11, regarding efficacy.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Feb-2008	BLA 125259		Cervarix Comment/Information Request Clinical	8115d254

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 100409 Protocol: 104888 Protocol: 106068 Protocol: 106072 Protocol: 107509 Protocol: 249553/004 Protocol: 269814/004 Protocol: 269814/005 Protocol: 732461/002 Protocol: M000026/016

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

## COMMENT/INFORMATION REQUEST

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Feb-2008	BLA 125259	Seq#: 0030	Cervarix Seq #: 0030 Amendment to Pending Application CMC	81154168

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:

ESG, ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Mar-2008	BLA 125259		Cervarix Comment/Information Request Other	81168774

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Mar-2008	BLA 125259		Cervarix Response to FDA Request/Comment Other	8116868e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical  RESPONSE TO FDA REQUEST/COMMENT

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Mar-2008	BLA 125259	Seq#: 0031	Cervarix Seq #: 0031 Amendment to Pending Application Efficacy	81170581

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Weining L. Hu	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Efficacy SUBTYPES: Efficacy

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:

GSK submitted this amendment as the fourth partial response, to the December 14th letter with this response, GSK has provided complete responses to all assay related questions.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Mar-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	8118bc4e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Mar-2008	BLA 125259		Cervarix Comment/Information Request Clinical	8118bc8d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Mar-2008	BLA 125259; BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Other Safety	8118bc71

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other; Clinical; Safety SUBTYPES: Other; Clinical; Safety Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Mar-2008	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	8118bc0d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Mar-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Other	8118bbce

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical SUBTYPES: Other; Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Mar-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	811ebabc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mr. Joseph A. Quander III	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Apr-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Other	811ebb18

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mr. Joseph A. Quander III	GlaxoSmithKline Ms. Weining L. Hu	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Apr-2008	BLA 125259		Cervarix Comment/Information Request Other	811d5bc1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Apr-2008	BLA 125259; BLA 125259	Seq#: 0032	Cervarix Seq #: 0032 Amendment to Pending Application Clinical Safety	8118ad64

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:

GSK providing the fifth partial response to the December 14th CR letter. Specifically, responses to the safety questions related to deaths in clinical trials, including updated information related to this category of events.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Apr-2008	BLA 125259		Cervarix General Memorandum Other	811afcb2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Helen Sullivan	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Apr-2008	BLA 125259		Cervarix Comment/Information Request Other	811d456f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Apr-2008	BLA 125259		Cervarix Comment/Information Request Other	811a64ee

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Apr-2008	BLA 125259	Seq#: 0033	Cervarix Seq #: 0033 General Correspondence Meeting Request	81194736

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Meeting Request SUBTYPES: Meeting Request

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Apr-2008	BLA 125259		Cervarix Comment/Information Request Other	811d5afb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Apr-2008	BLA 125259		Cervarix General Memorandum Meeting Request	811d45e9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: Meeting Request
	Dr. Helen Sullivan		SUBTYPES: Meeting Request

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-May-2008	BLA 125259		Cervarix General Memorandum Meeting Request	811d80c2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: Meeting Request
	Dr. Helen Sullivan		SUBTYPES: Meeting Request

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

04-May-2008 BLA 125259;  
BLA 125259Cervarix  
General Memorandum  
Meeting Request  
Other

811d6852

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Meeting Request SUBTYPES: Other; Meeting Request

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-May-2008	BLA 125259		Cervarix Comment/Information Request Other	811d8307

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-May-2008	BLA 125259; BLA 125259;		Cervarix Comment/Information Request	811d4674

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

BLA 125259

Clinical  
Other  
Statistical

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical; Statistical SUBTYPES: Other; Clinical; Statistical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-May-2008	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Other Safety	811d8297

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other; Safety SUBTYPES: Other; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-May-2008	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment	811d6311

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Clinical  
Statistical

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Clinical; Statistical
	Dr. Helen Sullivan		SUBTYPES: Clinical; Statistical
			Protocol: 580299/001
			Protocol: 580299/007

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-May-2008	BLA 125259		Cervarix Comment/Information Request Other	811d671c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Ms. Sharon Shapowal		SUBTYPES: Other
Ms. Helen S. Gemignani			SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-May-2008	BLA 125259	Seq#: 0034	Cervarix Seq #: 0034 Amendment to Pending Application	811b3cb8

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Safety

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Ms. Sharon Shapowal	Administration		SUBTYPES: Safety
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Safety

DESCRIPTION:

GSK submitted it's sixth partial response to the December 14, 2007 CR letter, specifically, we responses to the clinical safety questions related to serious adverse events (Question 2b), withdrawals from the clinical studies (Question 2e), and medically significant adverse events.

DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-May-2008	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Other Safety	811d67a5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Sharon Shapowal	Administration		SUBTYPES: Other; Safety
	Ms. Helen S. Gemignani		SUBTYPES: Other; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-May-2008	BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Clinical	811d66d7

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Other  
Safety

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Clinical; Safety SUBTYPES: Other; Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-May-2008	BLA 125259; BLA 125259	Seq#: 0035	Cervarix Seq #: 0035 Amendment to Pending Application Clinical Safety	811c0b03

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

DESCRIPTION:

GSK submitted the seventh partial response to the December 14th CR letter, specifically, responses to the clinical safety questions related to neuroinflammatory events (i.e. Questions 2fi, 2fii, 2g and 2h).

DESCRIPTORS:

ESG;ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-May-2008	BLA 125259; BLA 125259;		Cervarix General Memorandum	813ca2e6

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

BLA 125259

Clinical  
Other  
Safety

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Sharon Shapowal	Administration		SUBTYPES: Other; Clinical; Safety
	Ms. Helen S. Gemignani		SUBTYPES: Other; Clinical; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-May-2008	BLA 125259		Cervarix Response to FDA Request/Comment Other	811d65ae

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Sharon Shapowal	Administration		SUBTYPES: Other
	Ms. Helen S. Gemignani		SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-May-2008	BLA 125259; BLA 125259	Seq#: 0036	Cervarix Seq #: 0036 Amendment to Pending Application Clinical	811c591c

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Safety

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Ms. Sharon Shapowal	Administration		SUBTYPES: Clinical; Safety
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Clinical; Safety

DESCRIPTION:DESCRIPTORS:

ESG;ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-May-2008	BLA 125259; BLA 125259		Cervarix General Memorandum Meeting Agenda or Details Other	811d6684

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Ms. Sharon Shapowal		SUBTYPES: Other; Meeting Agenda or Details
Ms. Helen S. Gemignani			SUBTYPES: Other; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-May-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	811e5d8d

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Yolanda Davis	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-May-2008	BLA 125259; BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Other Statistical	811d484a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Helen Sullivan	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other; Clinical; Statistical SUBTYPES: Other; Clinical; Statistical Protocol: 580299/001 Protocol: 580299/007

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-May-2008	BLA 125259		Cervarix Response to FDA Request/Comment Other	8120e8e8

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Telephone Conversation	RESPONSE TO FDA REQUEST/COMMENT
Ms. Sharon Shapowal	Administration		SUBTYPES: Other
	Ms. Helen S. Gemignani		SUBTYPES: Other

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-May-2008	BLA 125259		Cervarix Comment/Information Request Other	8120dde8

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Ms. Sharon Shapowal		SUBTYPES: Other
Ms. Helen S. Gemignani			SUBTYPES: Other

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Jun-2008	BLA 125259; BLA 125259		Cervarix General Memorandum Meeting Agenda or Details Other	8120dcae

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

<b>FROM:</b>	<b>TO:</b>	<b>COMMUNICATION:</b>	<b>DOCTYPE &amp; SUBTYPE:</b>
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Meeting Agenda or Details SUBTYPES: Other; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Jun-2008	BLA 125259; BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Clinical Efficacy Meeting Agenda or Details Other Safety	8120dd58

<b>FROM:</b>	<b>TO:</b>	<b>COMMUNICATION:</b>	<b>DOCTYPE &amp; SUBTYPE:</b>
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Clinical; Safety; Meeting Agenda or Details; Efficacy SUBTYPES: Other; Clinical; Safety; Meeting Agenda or Details; Efficacy SUBINDEXING:

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Jun-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request	8120dbe8

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Clinical  
Safety

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Jun-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Safety	81210383

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical; Safety SUBTYPES: Clinical; Safety Protocol: 580299/001 Protocol: 580299/008 Protocol: 580299/009

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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11/10/2009 10:33:47 AM

Page: 126 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

18-Jun-2008 BLA 125259

Cervarix

812328c7

Comment/Information Request  
Clinical

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 580299/001 Protocol: 580299/008 Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Jun-2008	BLA 125259; BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Safety General Memorandum Meeting Agenda or Details	812a8131

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC; Safety SUBTYPES: CMC; Safety SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details  COMMENT/INFORMATION REQUEST

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Jun-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	8120db36

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Jun-2008	BLA 125259; BLA 125259		Cervarix General Memorandum Meeting Agenda or Details Other	8120dab6

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other; Meeting Agenda or Details SUBTYPES: Other; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Jun-2008	BLA 125259	Seq#: 0037	Cervarix Seq #: 0037 Amendment to Pending Application Other	81210229

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Other SUBTYPES: Other Protocol: 580299/008

DESCRIPTION:

GSK has taken the decision to postpone voluntarily the re-start of the review clock and to await the final results of the event triggered analysis of Study HPV-008 before initiating such action with respect to BLA 125259.

DESCRIPTORS:

ESG;ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Jun-2008	BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Clinical Efficacy Other Statistical	81232990

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Sharon Shapowal	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Other; Clinical; Statistical; Efficacy SUBTYPES: Other; Clinical; Statistical; Efficacy Protocol: 104820

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Jul-2008	BLA 125259	Cervarix	015-Day ADR Report N/A	81470efb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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GlaxoSmithKline

Food and Drug  
Administration

Correspondence

015-DAY ADR REPORT

SUBTYPES: N/A

SUBTYPES: N/A

SUBINDEXING:

ADRs: A0697970A

ADRs: B0471988A

ADRs: B0519583A

ADRs: B0524782A

ADRs: B0525232A

ADRs: B0525983A

ADRs: B0526899A

ADRs: B0527016A

ADRs: B0527288A

ADRs: D0057565A

ADRs: D0057878A

ADRs: D0057891A

ADRs: D0057892A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Jul-2008	BLA 125259; BLA 125259	Cervarix	General Memorandum	8125f30f

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Meeting Agenda or Details  
Other

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: Other; Meeting Agenda or Details
	Ms. Helen S. Gemignani		SUBTYPES: Other; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Jul-2008	BLA 125259		Cervarix General Memorandum Other	8123236e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Ms. Sharon Shapowal		SUBTYPES: Other
Ms. Helen S. Gemignani			SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Jul-2008	BLA 125259		Cervarix General Memorandum Meeting Request	8125f42b

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Request SUBTYPES: Meeting Request

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Jul-2008	BLA 125259		Cervarix Comment/Information Request Other	8123b207

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Jul-2008	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment CMC Safety	812a9e58

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: CMC; Safety
	Ms. Helen S. Gemignani		SUBTYPES: CMC; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Jul-2008	BLA 125259	Seq#: 0038	Cervarix Seq #: 0038 General Correspondence N/A	81230dd9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Dr. Clare Kahn, Ph.D.	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG; ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Jul-2008	BLA 125259		Cervarix Comment/Information Request CMC	812a9ef0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: CMC
Ms. Helen S. Gemignani			SUBTYPES: CMC

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jul-2008	BLA 125259; BLA 125259; BLA 125259; BLA 125259		Cervarix General Memorandum Efficacy Nonclinical Other Safety	812832b8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: Nonclinical; Other; Safety; Efficacy
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: Nonclinical; Other; Safety; Efficacy
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jul-2008	BLA 125259	Seq#: 0039	Cervarix Seq #: 0039 General Correspondence Other	812495cc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: Other

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Ph.D.

Dr. Norman Baylor, Ph.D.

SUBTYPES: Other  
Protocol: 580299/008DESCRIPTION:DESCRIPTORS:

ESG;ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Aug-2008	BLA 125259	Seq#: 0040	Cervarix Seq #: 0040 Minutes of Meeting N/A	8125157

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	MINUTES OF MEETING
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Aug-2008	BLA 125259; BLA 125259		Cervarix Comment/Information Request CMC Safety	8129e7dd

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: CMC; Safety
Ms. Helen S. Gemignani			SUBTYPES: CMC; Safety

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Aug-2008	BLA 125259	Seq#: 0041	Cervarix Seq #: 0041 General Correspondence Meeting Request	81265082

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: Meeting Request
Ph.D.	Dr. Norman Baylor, Ph.D.		SUBTYPES: Meeting Request

DESCRIPTION:DESCRIPTORS:

ESG;ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Aug-2008	BLA 125259		Cervarix Comment/Information Request Other	812a7f53

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: Other
Ms. Helen S. Gemignani			SUBTYPES: Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Aug-2008	BLA 125259; BLA 125259	Seq#: 0042	Cervarix Seq #: 0042 General Correspondence CMC Other	8128c0b8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Byron Bravo	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: CMC; Other SUBTYPES: CMC; Other

DESCRIPTION:

GSK submitted a description of the planned CMC changes and to outline the CMC data that will be filed in the Class 2 resubmission

DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Sep-2008	BLA 125259		Cervarix Comment/Information Request Other	8129e78f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Sep-2008	BLA 125259		Cervarix Response to FDA Request/Comment Other	812a7f9f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Other
	Ms. Helen S. Gemignani		SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Sep-2008	BLA 125259; BLA 125259; BLA 125259		Cervarix Comment/Information Request Clinical Efficacy Safety	812d58b7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: Clinical; Safety; Efficacy
Ms. Helen S. Gemignani			SUBTYPES: Clinical; Safety; Efficacy
			Protocol: 580299/008

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2008	BLA 125259	Cervarix		812e5745
		Response to FDA Request/Comment		
		Other		

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Other
	Ms. Helen S. Gemignani		SUBTYPES: Other
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Sep-2008	BLA 125259	Cervarix		812e57b7
		Response to FDA Request/Comment		
		Other		

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Other
	Ms. Helen S. Gemignani		SUBTYPES: Other
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Sep-2008	BLA 125259		Cervarix Response to FDA Request/Comment Other	812d5cc7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: Other
	Ms. Helen S. Gemignani		SUBTYPES: Other
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Sep-2008	BLA 125259		Cervarix Comment/Information Request Other	812e57cf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: Other
Ms. Helen S. Gemignani			SUBTYPES: Other
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Sep-2008	BLA 125259	Seq#: 0043	Cervarix Seq #: 0043 Response to FDA Request/Comment N/A	812b5186

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	812d7e67

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Oct-2008	BLA 125259		Cervarix General Memorandum Other	812d5e0d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Oct-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	812d7ef0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Oct-2008	BLA 125259	Seq#: 0044	Cervarix Seq #: 0044 General Correspondence Briefing Document	812ce661

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Briefing Document SUBTYPES: Briefing Document

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Oct-2008	BLA 125259; BLA 125259		Cervarix General Memorandum Advisory Committee Meeting Meeting Agenda or Details	812d585c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Elizabeth Sutkowski	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Advisory Committee Meeting; Meeting Agenda or Details SUBTYPES: Advisory Committee Meeting; Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

05-Nov-2008 BLA 125259

Cervarix  
Comment/Information Request  
CMC

8131e62c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Byron Bravo	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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18-Nov-2008 BLA 125259

Cervarix  
General Memorandum  
Meeting Agenda or Details

8135be93

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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21-Nov-2008 BLA 125259

Seq#: 0045

Cervarix Seq #: 0045  
Amendment to Pending Application

8131f303

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ECTD;SAFE;ESG

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Nov-2008	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	813512f7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Mr. Matthew Whitman		SUBTYPES: Meeting Agenda or Details
Ms. Helen S. Gemignani			SUBTYPES: Meeting Agenda or Details

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Dec-2008	BLA 125259	Seq#: 0046	Cervarix Seq #: 0046 Response to FDA Request/Comment N/A	8132ed5e

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

ECTD;SAFE;ESG

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Dec-2008	BLA 125259	Seq#: 0047	Cervarix Seq #: 0047 General Correspondence CMC	8134865b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Mr. Byron Bravo	Administration		SUBTYPES: CMC
	Dr. Norman Baylor, Ph.D.		SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:

ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Dec-2008	BLA 125259		Cervarix General Memorandum Other	813c02b1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: Other
	Ms. Helen S. Gemignani		SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Jan-2009	BLA 125259		Cervarix Comment/Information Request Other	813bedfc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Jan-2009	BLA 125259		Cervarix Comment/Information Request Other	813bf249

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Other SUBTYPES: Other

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Feb-2009	BLA 125259		Cervarix General Memorandum Clinical	813d53ee

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	FAX/E-mail	GENERAL MEMORANDUM  GENERAL MEMORANDUM SUBTYPES: Clinical; N/A SUBTYPES: Clinical; N/A Protocol: 580299/008

DESCRIPTION:

Provided Norman Baylor the slides on the pivotal efficacy trial for Cervarix destined for ACIP Feb 25th.

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Mar-2009	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	813ca31b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Sharon Shapowal	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Mar-2009	BLA 125259; BLA 125259		Cervarix General Memorandum Efficacy Meeting Agenda or Details	813ed0b2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Nicholas Perombelon	Administration		SUBTYPES: Meeting Agenda or Details; Efficacy
	Ms. Helen S. Gemignani		SUBTYPES: Meeting Agenda or Details; Efficacy
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Mar-2009	BLA 125259; BLA 125259		Cervarix Resubmission Clinical CMC	813e96e0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	RESUBMISSION
Mr. Matthew Whitman	Administration		SUBTYPES: CMC; Clinical
	Dr. Norman Baylor, Ph.D.		SUBTYPES: CMC; Clinical

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 106636  
Protocol: 107682  
Protocol: 107863  
Protocol: 108464  
Protocol: 109616/109624/109625  
Protocol: 111103  
Protocol: 111567  
Protocol: 580299/007  
Report: 580299/007  
Protocol: 580299/008  
Report: 580299/008  
Reports: VAL/HPV16PNTPCV02  
Reports: VAL/HPV18PNTPCV02

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Mar-2009	BLA 125259		Cervarix General Memorandum N/A	8140c4eb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Mar-2009	BLA 125259		Cervarix General Memorandum N/A	8140c4c8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/007
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Apr-2009	BLA 125259		Cervarix Comment/Information Request N/A	8140c46e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:

FDa advised GSK to review the original submission and, if necessary, submit a revised proposal for pediatric studies based on Section 505B [355c] of the Federal Food, Drug and Cosmetic Act (Research into Pediatric Uses for Drugs and Biological Products) by April 30, 2009, as an amendment to the BLA.

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Apr-2009	BLA 125259	Seq#: 0049	Cervarix Seq #: 0049 Amendment: Other N/A	8140c239

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT: OTHER
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG:ECTD

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Apr-2009	BLA 125259		Cervarix General Memorandum N/A	8142f6e1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Apr-2009	BLA 125259		Cervarix	8142206d

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

General Memorandum  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Apr-2009	BLA 125259		Cervarix General Teleconference Clinical	8142e27d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	Food and Drug Administration Ms. Helen S. Gemignani	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Apr-2009	BLA 125259		Cervarix General Correspondence Status Update	8143119d

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mr. Wellington Sun	GlaxoSmithKline Mr. Matthew Whitman	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Status Update SUBTYPES: Status Update

DESCRIPTION:

FDA designated the resubmission of Cervarix a complete class 2 response therefore assigning Sep 29, 2009 as the user fee goal date.

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Apr-2009	BLA 125259	Seq#: 0050	Cervarix Seq #: 0050 Amendment to Pending Application Other	8142a0de

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

ESG:ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Apr-2009	BLA 125259		Cervarix General Memorandum N/A	8143ad2f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Matthew Whitman  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Apr-2009	BLA 125259		Cervarix General Memorandum N/A	8143ac75

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A Protocol: 107682

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-May-2009	BLA 125259		Cervarix Comment/Information Request N/A	8143ac12

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-May-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81447adf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-May-2009	BLA 125259; BLA 125259	Seq#: 0051	Cervarix Seq #: 0051 Amendment to Pending Application Other Safety	814410e9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Dr. Edward M. Yuhas,	Administration		SUBTYPES: Other; Safety
Ph.D.	Dr. Norman Baylor, Ph.D.		SUBTYPES: Other; Safety



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-May-2009	BLA 125259		Cervarix Comment/Information Request N/A	81451eaf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-May-2009	BLA 125259		Cervarix Comment/Information Request N/A	81451e89

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-May-2009	BLA 125259; BLA 125259		Cervarix General Teleconference Advisory Committee Meeting Other	8145fb95

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: Other; Advisory Committee Meeting SUBTYPES: Other; Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-May-2009	BLA 125259		Cervarix General Teleconference Advisory Committee Meeting	81478bb4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Christine Walsh, R.N.	GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: Advisory Committee Meeting SUBTYPES: Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-May-2009	BLA 125259		Cervarix General Memorandum N/A	8152b78e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Jun-2009	BLA 125259	Seq#: 0052	Cervarix Seq #: 0052 Response to FDA Request/Comment N/A	81462c8c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Edward M. Yuhas, Ph.D.	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Jun-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8147b558

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Jun-2009	BLA 125259	Seq#: 0053	Cervarix Seq #: 0053 Response to FDA Request/Comment N/A	814704f5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Jun-2009	BLA 125259; BLA 125259		Cervarix General Memorandum Phase IV Commitment Safety	81510091

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Phase IV Commitment; Safety SUBTYPES: Phase IV Commitment; Safety Protocol: 111103

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Jun-2009	BLA 125259		Cervarix Comment/Information Request N/A	814863cb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Jun-2009	BLA 125259		Cervarix General Memorandum N/A	81486464

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Jun-2009	BLA 125259		Cervarix Comment/Information Request N/A	814866b6

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Jun-2009	BLA 125259		Cervarix	81488029

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Response to FDA Request/Comment  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jun-2009	BLA 125259	Cervarix	Response to FDA Request/Comment N/A	814889f2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jun-2009	BLA 125259	Cervarix	General Memorandum N/A	8152bff2

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jun-2009	BLA 125259		Cervarix Comment/Information Request N/A	8152c0c0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jun-2009	BLA 125259		Cervarix General Memorandum N/A	81529300

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Ms. Helen S. Gemignani	Mr. Nicholas Perombelon		SUBTYPES: N/A
			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jun-2009	BLA 125259; BLA 125259		Cervarix Comment/Information Request Safety General Memorandum Advisory Committee Meeting	815100d4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani	Mr. Nicholas Perombelon		SUBTYPES: Safety SUBTYPES: Safety SUBTYPES: Advisory Committee Meeting SUBTYPES: Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Jun-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81529380

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Jun-2009	BLA 125259		Cervarix General Memorandum N/A	815293d9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Mr. Nicholas Perombelon		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Jun-2009	BLA 125259		Cervarix General Memorandum N/A	815294aa

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Nicholas Perombelon  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Jun-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8152946d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 111103

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jun-2009	BLA 125259		Cervarix General Memorandum Meeting Agenda or Details	8151046b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Meeting Agenda or Details SUBTYPES: Meeting Agenda or Details

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 113522

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jun-2009	BLA 125259		Cervarix General Memorandum Phase IV Commitment	81510117

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Nicholas Perombelon	Administration		SUBTYPES: Phase IV Commitment
	Ms. Helen S. Gemignani		SUBTYPES: Phase IV Commitment
			Protocol: 113522

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jun-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81492e86

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 110659

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 110886

Protocol: 111507

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jun-2009	BLA 125259	Cervarix General Memorandum N/A		8149393f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jun-2009	BLA 125259	Cervarix General Teleconference N/A		81492dd3

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: N/A SUBTYPES: N/A Protocol: 110659

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 110886

Protocol: 111507

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jun-2009	BLA 125259		Cervarix Comment/Information Request N/A	814add7b

FROM: TO: COMMUNICATION: DOCTYPE & SUBTYPE:

Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 110659 Protocol: 110886 Protocol: 111507
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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	81498257

FROM: TO: COMMUNICATION: DOCTYPE & SUBTYPE:

GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Mr. Matthew Whitman Administration  
Ms. Helen S. Gemignani

SUBTYPES: Clinical  
SUBTYPES: Clinical  
Protocol: 106636  
Protocol: 110659  
Protocol: 110886  
Protocol: 111507  
Protocol: 580299/011

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	8149827c

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814add93

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 106636 Protocol: 110659 Protocol: 110886 Protocol: 111507 Protocol: 580299/011

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment Safety	8151052d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Safety SUBTYPES: Safety Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Jul-2009	BLA 125259	Seq#: 0054	Cervarix Seq #: 0054	8149ba19

11/10/2009 10:33:48 AM

Page: 172 of 299



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

General Correspondence  
CMC

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Mr. Byron Bravo	Administration		SUBTYPES: CMC
	Dr. Norman Baylor, Ph.D.		SUBTYPES: CMC

DESCRIPTION:

ESG;ECTD;SAFE

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Jul-2009	BLA 125259		Cervarix General Memorandum N/A	814ad833

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Jul-2009	BLA 125259	Seq#: 0055	Cervarix Seq #: 0055 General Correspondence N/A	81494ccf

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814ad8a7

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Jul-2009	BLA 125259	Seq#: 0056	Cervarix Seq #: 0056 Amendment to Pending Application Safety	8149d038

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Dr. Edward M. Yuhas,	Administration		SUBTYPES: Safety
Ph.D.	Dr. Norman Baylor, Ph.D.		SUBTYPES: Safety
			Protocol: 580299/008
			Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814adccf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	815354d9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Matthew Whitman  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Jul-2009	BLA 125259	Cervarix		814add4d
		Response to FDA Request/Comment		
		N/A		

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/008
			Protocol: 580299/010

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Jul-2009	BLA 125259	Cervarix		814b1310
		Comment/Information Request		
		N/A		

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Ms. Helen S. Gemignani

SUBTYPES: N/A

Protocol: 580299/010

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Jul-2009	BLA 125259	Seq#: 0057	Cervarix Seq #: 0057 General Correspondence Advertising/Promotion	814a8768

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	GENERAL CORRESPONDENCE
Mr. Matthew Whitman	Administration		SUBTYPES: Advertising/Promotion
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Advertising/Promotion

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Jul-2009	BLA 125259		Cervarix General Memorandum N/A	814ad8fa

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Jul-2009	BLA 125259		Cervarix Comment/Information Request Labeling	814b11f3

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Labeling SUBTYPES: Labeling

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment Labeling	814b121d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Labeling SUBTYPES: Labeling

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814b0dc1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814b349f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814b29aa

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814b62b4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814cc18b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Jul-2009	BLA 125259	Seq#: 0058	Cervarix Seq #: 0058 General Correspondence Other	814aeed1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Teresa Ward	Food and Drug Administration Mr. Gilliam Conley	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814bd4db

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814c4388

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 107638 Protocol: 111712 Protocol: 112024 Protocol: 112485 Protocol: 113618 Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814bd426

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Jul-2009	BLA 125259		Cervarix General Memorandum N/A	814c42bc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Jul-2009	BLA 125259	Cervarix	Response to FDA Request/Comment Safety	815110a2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: Safety
	Ms. Helen S. Gemignani		SUBTYPES: Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Jul-2009	BLA 125259	Cervarix	Response to FDA Request/Comment N/A	814c41ba

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jul-2009	BLA 125259		Cervarix General Memorandum N/A	814c0367

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jul-2009	BLA 125259	Seq#: 0059	Cervarix Seq #: 0059 Amendment to Pending Application N/A	814b9e07

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jul-2009	BLA 125259		Cervarix	814c0401

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Comment/Information Request  
N/A

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jul-2009	BLA 125259		Cervarix General Memorandum N/A	81535251

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Jul-2009	BLA 125259		Cervarix Comment/Information Request Safety	815106a3

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Safety SUBTYPES: Safety Protocol: 580299/009

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814c03bb

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814c0390

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani			SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008 Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814c0300

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani			SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Jul-2009	BLA 125259		Cervarix Comment/Information Request Safety	8151119b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Safety SUBTYPES: Safety
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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	81535627

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Jul-2009	BLA 125259		Cervarix General Memorandum N/A	814c02be

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Ms. Helen S. Gemignani

SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814c1fa6

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Robin Levis		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814c1fc3

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Robin Levis		SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814c1f6f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: BEP113522

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259	Seq#: 0060	Cervarix Seq #: 0060 Response to FDA Request/Comment N/A	814be466

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A
			Protocol: 580299/009

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814c776e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Laura C. Montague	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814c76cb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Laura C. Montague	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259		Cervarix Comment/Information Request N/A	814c67ab

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Laura C. Montague	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Jul-2009	BLA 125259		Cervarix General Memorandum N/A	814c450e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Laura C. Montague	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814c67ce

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Laura C. Montague	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Aug-2009	BLA 125259	Seq#: 0061	Cervarix Seq #: 0061 Amendment to Pending Application Safety	814c455d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Edward M. Yuhas, Ph.D.	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Safety SUBTYPES: Safety Protocol: 104798 Protocol: 105881 Protocol: 108464 Protocol: 108933 Protocol: 110659

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814cd31d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Laura C. Montague	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814cd351

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Laura C. Montague	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814cd33a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Laura C. Montague	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814cd363

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Laura C. Montague	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814cd3f4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Laura C. Montague		SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814cd3a8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Laura C. Montague			SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814cd37a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Laura C. Montague		SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814cd394

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Laura C. Montague			SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Aug-2009	BLA 125259; BLA 125259; BLA 125259; BLA 125259; BLA 125259; BLA 125259	Seq#: 0062	Cervarix Seq #: 0062 Amendment to Pending Application N/A General Correspondence Advisory Committee Meeting Briefing Document Clinical Efficacy Safety	814cb8da

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: N/A SUBTYPES: N/A SUBTYPES: Clinical; Safety; Advisory Committee Meeting; Briefing Document; Efficacy SUBTYPES: Clinical; Safety; Advisory Committee Meeting; Briefing Document; Efficacy  Protocol: 580299/001 Protocol: 580299/007 Protocol: 580299/008 Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:

ESG; ECTD; SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Aug-2009	BLA 125259	Seq#: 0063	Cervarix Seq #: 0063 Amendment to Pending Application Other	814c9892
FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:	
GlaxoSmithKline Mr. Byron Bravo	Food and Drug Administration	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Other	

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Dr. Norman Baylor, Ph.D.

SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Aug-2009	BLA 125259		Cervarix General Correspondence Advisory Committee Meeting	814c6c80

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Christine Walsh, R.N.	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Advisory Committee Meeting SUBTYPES: Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814cd403

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Laura C. Montague	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Aug-2009	BLA 125259	Seq#: 0064	Cervarix Seq #: 0064 Response to FDA Request/Comment N/A	814cd440

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814d0da5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814d0d7e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814d0d8f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814d21cc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814d0d47

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814d0d6d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
12-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814d230b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Aug-2009	BLA 125259	Seq#: 0065	Cervarix Seq #: 0065 Response to FDA Request/Comment N/A	814d074b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 113522

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e75af

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814d42dc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814d4146

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

13-Aug-2009 BLA 125259

Cervarix  
Response to FDA Request/Comment  
N/A

814d40ab

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Christine Walsh, R.N.		SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Aug-2009	BLA 125259	Seq #: 0066	Cervarix Seq #: 0066 Response to FDA Request/Comment N/A	814d3df5

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	815090e2

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Arthur Berger Jr.	Administration		SUBTYPES: N/A
	Dr. Carmen M. Collazo		SUBTYPES: N/A
			Protocol: 106372

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e1f88

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Aug-2009	BLA 125259		Cervarix General Correspondence N/A	814db8f3

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Heather Murray	GlaxoSmithKline Mr. Nicholas Perombelon	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: N/A SUBTYPES: N/A Protocol: 104772 Protocol: 580299/001 Protocol: 580299/002 Protocol: 580299/003 Protocol: 580299/004 Protocol: 580299/005 Protocol: 580299/007 Protocol: 580299/008 Protocol: 580299/012

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Aug-2009	BLA 125259		Cervarix General Memorandum Advisory Committee Meeting	815111b1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Advisory Committee Meeting SUBTYPES: Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
20-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e1a51

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Aug-2009	BLA 125259		Cervarix General Memorandum Advisory Committee Meeting	815111cf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: Advisory Committee Meeting SUBTYPES: Advisory Committee Meeting

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Aug-2009	BLA 125259		Cervarix	814e1fea

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Comment/Information Request

N/A

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e2024

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e7937

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 104479
			Protocol: 109890

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
21-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment CMC	814e7891

---

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: CMC
	Ms. Helen S. Gemignani		SUBTYPES: CMC

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814f06ea

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e2045

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e2086

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Matthew Whitman  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814e21e5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Christine Walsh, R.N.	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e2205

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Christine Walsh, R.N.	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Aug-2009	BLA 125259		Cervarix General Teleconference N/A	814f05b5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	Telephone Conversation	GENERAL TELECONFERENCE SUBTYPES: N/A SUBTYPES: N/A Protocol: 110659 Protocol: 580299/008 Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e3ff8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e5c4e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e43a5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Lisa Stockbridge, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e987e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814e3dfa

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Christine Walsh, R.N.	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814e3d33

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e3c0c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e5b48

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e5bbe

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Yes

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e5b85

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Aug-2009	BLA 125259	Seq#: 0067	Cervarix Seq #: 0067 Response to FDA Request/Comment N/A	814e2248

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814f061a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814f067a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814e9837

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/008
			Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e97fa

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11/10/2009 10:33:49 AM				Page: 222 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

27-Aug-2009 BLA 125259

Cervarix

814e6e1a

Response to FDA Request/Comment

N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Dr. Edward M. Yuhas,	Administration		SUBTYPES: N/A
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

The attachment (on Cervarix) contains information that can not go into CARDS; the attachment was given to Yvette Clarkto handle.

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

27-Aug-2009 BLA 125259

Cervarix

814eb973

Response to FDA Request/Comment

N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

27-Aug-2009 BLA 125259

Cervarix

814eadb8

General Teleconference

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Telephone Conversation	GENERAL TELECONFERENCE
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814e9925

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814e98bc

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Christine Walsh, R.N.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Aug-2009	BLA 125259		Cervarix	814e9a3f
			Response to FDA Request/Comment	
			N/A	

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Aug-2009	BLA 125259		Cervarix	814e99a2
			Comment/Information Request	
			N/A	

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Matthew Whitman  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Aug-2009	BLA 125259; BLA 125259		Cervarix Response to FDA Request/Comment Patent Information Safety	814ee044

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Edward M. Yuhas, Ph.D.	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Patent Information; Safety SUBTYPES: Patent Information; Safety

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Aug-2009	BLA 125259		Cervarix Comment/Information Request N/A	814ead6f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Aug-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814eaf56

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Byron Bravo	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
31-Aug-2009	BLA 125259		Cervarix General Memorandum N/A	814ee334

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Christine Walsh, R.N.	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814ee2de

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	Telephone Conversation	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Sep-2009	BLA 125259		Cervarix Comment/Information Request Advertising/Promotion	814f2e22

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Lisa Stockbridge, Ph.D.	GlaxoSmithKline Ms. Donna Boyce	Correspondence	COMMENT/INFORMATION REQUEST SUBTYPES: Advertising/Promotion SUBTYPES: Advertising/Promotion

DESCRIPTION:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81506fdf

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81470620

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Christine Walsh, R.N.		SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814f05ec

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814ee2ef

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	81521d92

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814f06dc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	8140158b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	81400897

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814f080c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/008
			Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814f0756

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11/10/2009 10:33:49 AM				Page: 233 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

02-Sep-2009 BLA 125259

Cervarix  
Comment/Information Request  
N/A

814f072b

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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02-Sep-2009 BLA 125259

Cervarix  
Comment/Information Request  
N/A

814f0683

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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04-Sep-2009 BLA 125259

Cervarix  
Comment/Information Request

814fd700

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814f334b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
04-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	81521ddf

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8150d4de

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	8146d72f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Matthew Whitman  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814fd7c7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814fd884

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: N/A
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 107682

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 109616/109624/109625

Protocol: 110886

Protocol: 580299/001

Protocol: 580299/012

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	814fd92c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	GENERAL MEMORANDUM
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	81521e86

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Ms. Cynthia D'Ambrosio,		SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Ms. Helen S. Gemignani Ph.D.

SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81521e3c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: N/A
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 109616/109624/109625
			Protocol: 109628
			Protocol: 580299/001
			Protocol: 580299/007
			Protocol: 580299/008
			Protocol: 580299/009
			Protocol: 580299/012
			Protocol: 580299/013

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Sep-2009	BLA 125259		Cervarix Transmittal of Advertisements and Promotional Materials	8150741c

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

N/A

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL MATERIALS
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. The Central Document		SUBTYPES: N/A
	Control Room		

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Sep-2009	BLA 125259		Cervarix	814fd56f
			Comment/Information Request	
			N/A	

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

---

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259		Cervarix	814fd6a7
			Comment/Information Request	
			N/A	

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814fd5c9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814fdd09

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Mr. Matthew Whitman Administration  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8150d3cd

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	81503364

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259	Cervarix		814ff879
		Comment/Information Request		
		N/A		

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani	Mr. Matthew Whitman		SUBTYPES: N/A
			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259	Cervarix		814fddb8
		Comment/Information Request		
		N/A		

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani	Mr. Matthew Whitman		SUBTYPES: N/A
			SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814fdd71

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814fe345

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814fd467

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814fd4fc

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814fdc59

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814fde12

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814ff8e5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	Correspondence	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
15-Sep-2009	BLA 125259		Cervarix Acknowledgement N/A	814ff997

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	ACKNOWLEDGEMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Sep-2009	BLA 125259		Cervarix	814ffa7b

11/10/2009 10:33:49 AM

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Response to FDA Request/Comment  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	814ffa4a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	814ffa0a

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: N/A
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Sep-2009	BLA 125259		Cervarix Comment/Information Request Clinical	81548140

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: Clinical
Ms. Helen S. Gemignani			SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	81501cf2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Administration Mr. Matthew Whitman  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Sep-2009	BLA 125259	Seq#: 0068	Cervarix Seq #: 0068 Request to Withdraw N/A	814fe125

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Byron Bravo	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	REQUEST TO WITHDRAW SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81501d2c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
17-Sep-2009	BLA 125259	Seq#: 0069	Cervarix Seq #: 0069 Amendment to Pending Application CMC	8150144e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Ms. Linda S. Kramer	Administration		SUBTYPES: CMC
	Ms. Mary Malarkey		SUBTYPES: CMC

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	81503e9c

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	81503e79

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	81505495

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
18-Sep-2009	BLA 125259; BLA 125259; BLA 125259	Seq#: 0070	Cervarix Seq #: 0070 Amendment to Pending Application Efficacy Labeling Safety	815027aa

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Safety; Labeling; Efficacy SUBTYPES: Safety; Labeling; Efficacy Protocol: 110659 Protocol: 580299/008

DESCRIPTION:

GSK provided a summary document, the annexed statistical analysis and HPV-048 study report synopsis in. Additionally in response to FDA , GSK prepared and provided a discussion document (FDA Discussion Document -Spontaneous Abortions Around Vaccination) as well as draft prescribing information updated and submitted to CBER by e-mail on September 16, 2009.

DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	8150c3af

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Sep-2009	BLA 125259; BLA 125259		Cervarix Comment/Information Request Labeling Safety	81512a53

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Lori Austin-Hansberry	GlaxoSmithKline Dr. Edward M. Yuhas, Ph.D.	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Safety; Labeling SUBTYPES: Safety; Labeling

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment Safety	8151296e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Edward M. Yuhas, Ph.D.	Food and Drug Administration Mrs. Lori Austin-Hansberry	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Safety SUBTYPES: Safety

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8150c39b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	8150c356

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8150c3d0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: N/A
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Sep-2009	BLA 125259	Seq#: 0071	Cervarix Seq #: 0071 Amendment to Pending Application N/A	81506a57

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A
			Protocol: 580299/008

DESCRIPTION:

In response to FDA requests, GSK provided an HPV-008 summary table of persistent infection for individual HPV types; an HPV-008 TVC cohort table to assist Dr. Miller with her VRBPAC slides and as requested from Ms. Gemignani, an explanation of a discrepancy in numbers between Table 13 of the VRBPAC Briefing document and Supplement 192 of the HPV-008 report.

DESCRIPTORS:

ESG:ECTD;SAFE

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Sep-2009	BLA 125259	Seq#: 0072	Cervarix Seq #: 0072 Amendment to Pending Application CMC	81504d71

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Byron Bravo	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:

GSK provided stability updates as well as other CMC information as requested by the FDA

DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	8150c45d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Sep-2009	BLA 125259		Cervarix General Memorandum N/A	8150c426

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	FAX/E-mail	GENERAL MEMORANDUM SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Sep-2009	BLA 125259	Seq#: 0073	Cervarix Seq #: 0073 Amendment to Pending Application N/A	814fdece

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Dr. Edward M. Yuhas, Ph.D.	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

24-Sep-2009 BLA 125259

Cervarix

8150c4a2

Response to FDA Request/Comment  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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24-Sep-2009 BLA 125259

Cervarix

8150c4c3

General Memorandum  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	GENERAL MEMORANDUM
Administration	Mr. Nicholas Perombelon		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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24-Sep-2009 BLA 125259

Cervarix

8150cba6

General Teleconference  
N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Telephone Conversation	GENERAL TELECONFERENCE
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Lisa Stockbridge,		SUBTYPES: N/A
	Ph.D.		

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Sep-2009	BLA 125259		Cervarix	8150cdc7
			Comment/Information Request	
			N/A	

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Sep-2009	BLA 125259		Cervarix	8150cdd6
			Response to FDA Request/Comment	
			N/A	

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
24-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	8150d59e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	Correspondence	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	815110f5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Mr. Matthew Whitman Administration  
Ms. Helen S. Gemignani

SUBTYPES: N/A  
SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	8150de80

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
25-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	81510ffb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	815110d9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Sep-2009	BLA 125259	Seq#: 0074	Cervarix Seq #: 0074 Amendment to Pending Application CMC	8150f337

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Byron Bravo	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: CMC SUBTYPES: CMC

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Sep-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81511113

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
28-Sep-2009	BLA 125259		Cervarix Comment/Information Request Advertising/Promotion	81511d02

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Lisa Stockbridge, Ph.D.	GlaxoSmithKline Mr. Matthew Whitman	Correspondence	COMMENT/INFORMATION REQUEST SUBTYPES: Advertising/Promotion SUBTYPES: Advertising/Promotion SUBINDEXING: Material: POT - Professional Other - CVX240RO

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	815149e9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Sep-2009	BLA 125259	Seq#: 0075	Cervarix Seq #: 0075 Amendment to Pending Application Labeling	8150bb7b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: Labeling SUBTYPES: Labeling

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Sep-2009	BLA 125259		Cervarix Comment/Information Request N/A	81516bd1

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Sep-2009	BLA 125259		Cervarix Comment/Information Request Clinical	81548177

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Oct-2009	BLA 125259	Cervarix	Comment/Information Request N/A	81516d1b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
01-Oct-2009	BLA 125259	Cervarix	Comment/Information Request N/A	8151832e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

01-Oct-2009 BLA 125259

Cervarix

81518341

Comment/Information Request

N/A

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani	Mr. Matthew Whitman		SUBTYPES: N/A
			SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

02-Oct-2009 BLA 125259

Cervarix

8151838b

Response to FDA Request/Comment

N/A

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Ms. Helen S. Gemignani		SUBTYPES: N/A
			SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

02-Oct-2009 BLA 125259

Cervarix

815183b8

Comment/Information Request

N/A



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:

GSK submitted marked-up and clean versions from e-mails recieved from Ms. Helen Gemignani dated September 29, 2009 and October 1, 2009 which contained revised draft labeling from CBER. GSK also provided supporting tables for numbers of deaths and SAEs in 10-25 year olds.

DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81518378

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: N/A
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8151ef28

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Nicholas Perombelon		SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Ms. Helen S. Gemignani

SUBTYPES: N/A

Protocol: 104820

Protocol: 106636

Protocol: 109616/109624/109625

Protocol: 109628

Protocol: 580299/008

Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8151efd7

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8151ef8a

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8151eda9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	8151ede9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Mr. Nicholas Perombelon Administration  
Ms. Helen S. Gemignani

SUBTYPES: Clinical  
SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8151ee58

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8151ee9a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A Protocol: 104820

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8151f011

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

---

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259	Seq#: 0076	Cervarix Seq #: 0076 Amendment to Pending Application N/A	81514720

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Protocol: 106636  
Protocol: 109616/109624/109625  
Protocol: 109628  
Protocol: 580299/008  
Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
02-Oct-2009	BLA 125259	Cervarix	Comment/Information Request N/A	8151eee8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 104820 Protocol: 106636 Protocol: 109616/109624/109625 Protocol: 109628 Protocol: 580299/008 Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

06-Oct-2009 BLA 125259

Cervarix

8151ea63

Comment/Information Request  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

07-Oct-2009 BLA 125259

Cervarix

8151ebc4

Comment/Information Request  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Lori Austin-Hansberry	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE: APPLICATION: SER/SUPP/SEQ #: RE LINE:

DOC ID:

07-Oct-2009 BLA 125259

Cervarix

8151e9c3

Comment/Information Request

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A Protocol: 104820 Protocol: 106636 Protocol: 109616/109624/109625 Protocol: 109628 Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	81548440

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical Protocol: 104820 Protocol: 106636 Protocol: 109616/109624/109625 Protocol: 109628 Protocol: 580299/008 Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment Clinical	815483a4

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Mrs. Lori Austin-Hansberry	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: Clinical SUBTYPES: Clinical

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
07-Oct-2009	BLA 125259		Cervarix Comment/Information Request Electronic Format	8151ffe9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. David A. Donohue	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: Electronic Format SUBTYPES: Electronic Format

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

No

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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07-Oct-2009	BLA 125259	Cervarix		8151ffda
		Response to FDA Request/Comment		
		N/A		

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

No

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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07-Oct-2009	BLA 125259	Cervarix		8151ffc9
		Comment/Information Request		
		N/A		

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:QC COMPLETED: DATE REFERENCED:

No

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	815214bb

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Lori Austin-Hansberry	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Oct-2009	BLA 125259	Sup#:	Cervarix Sup #: Supplement: Prior Approval Establishment Description	81519a7e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	Correspondence	SUPPLEMENT: PRIOR APPROVAL SUBTYPES: Establishment Description SUBTYPES: Establishment Description

DESCRIPTION:

GSK submitted an EST PAS application which provides for a comparability protocol for assessing the effect of implementation of the Lynx S2S connector in the Rixensart and Wavre, Begium sites

DESCRIPTORS:

ESG;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
11/10/2009 10:33:50 AM				Page: 279 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

08-Oct-2009 BLA 125259

Cervarix

815214db

Response to FDA Request/Comment  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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08-Oct-2009 BLA 125259

Cervarix

815214ec

Comment/Information Request  
N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Ms. Cynthia D'Ambrosio,		SUBTYPES: N/A
Ms. Helen S. Gemignani	Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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08-Oct-2009 BLA 125259

Cervarix

815214fd

Response to FDA Request/Comment

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

N/A

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A
			Protocol: 580299/009

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8152150e

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Ms. Cynthia D'Ambrosio,	Administration		SUBTYPES: N/A
Ph.D.	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	815214ca

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Mrs. Lori Austin-Hansberry	Mr. Nicholas Perombelon		SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8151fed2

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani	Mr. Matthew Whitman		SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
08-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	81539fba

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani	Ms. Cynthia D'Ambrosio, Ph.D.		SUBTYPES: N/A
			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8153e52a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Ms. Helen S. Gemignani	Mr. Matthew Whitman		SUBTYPES: N/A
			SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81530944

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Nicholas Perombelon	Ms. Helen S. Gemignani		SUBTYPES: N/A
			SUBTYPES: N/A

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8153e478

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Mrs. Lori Austin-Hansberry	GlaxoSmithKline Mr. Nicholas Perombelon	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8153e455

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Mrs. Lori Austin-Hansberry	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8153e4af

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Nicholas Perombelon	Food and Drug Administration Mrs. Lori Austin-Hansberry	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
09-Oct-2009	BLA 125259	Seq#: 0077	Cervarix Seq #: 0077 Amendment to Pending Application N/A	81521aec

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	AMENDMENT TO PENDING APPLICATION SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Submitted GSK's annotated and clean versions of the prescribing information, as well as responses to CBER's September 16, 2009 and September 30, 2009 questions e-mailed to Ms. Gemignani on October 2, 2009 with respect to analyses of SAEs, timeframes for following the various events, and the suggestion to use self controls,

DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
10-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	81530924

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Ms. Helen S. Gemignani		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
13-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	81530980

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	FAX/E-mail	COMMENT/INFORMATION REQUEST
Administration	Mr. Matthew Whitman		SUBTYPES: N/A
Ms. Helen S. Gemignani			SUBTYPES: N/A

DESCRIPTION:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Oct-2009	BLA 125259		Cervarix Comment/Information Request N/A	8153e547

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Ms. Helen S. Gemignani	GlaxoSmithKline Mr. Matthew Whitman	FAX/E-mail	COMMENT/INFORMATION REQUEST SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Oct-2009	BLA 125259		Cervarix Response to FDA Request/Comment N/A	8153e573

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Cynthia D'Ambrosio, Ph.D.	Food and Drug Administration Ms. Helen S. Gemignani	FAX/E-mail	RESPONSE TO FDA REQUEST/COMMENT SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Oct-2009	BLA 125259	Seq#: 0079	Cervarix Seq #: 0079 Amendment to Pending Application Labeling	8152768d

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Mr. Matthew Whitman	Administration		SUBTYPES: Labeling
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Labeling

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Oct-2009	BLA 125259	Seq#: 0078	Cervarix Seq #: 0078 Amendment to Pending Application Labeling	815275b8

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Mr. Matthew Whitman	Administration		SUBTYPES: Labeling
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Labeling

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
14-Oct-2009	BLA 125259	Seq#: 0080	Cervarix Seq #: 0080 Amendment to Pending Application N/A	81529bd9

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	AMENDMENT TO PENDING APPLICATION
Mr. Matthew Whitman	Administration		SUBTYPES: N/A
	Dr. Norman Baylor, Ph.D.		SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Oct-2009	BLA 125259		Cervarix Transmittal of Advertisements and Promotional Materials Advertising/Promotion	81531abd

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL MATERIALS
Mr. Matthew Whitman	Administration		SUBTYPES: Advertising/Promotion
	Ms. The Central Document		SUBTYPES: Advertising/Promotion
	Control Room		SUBINDEXING:
			Material: PPO - Professional Print - Other - CVX275R0: Dear Customer - Announcement Letter
			Material: PPO - Professional Print - Other - CVX274R0: Dear Customer - Announcement Template Letter

DESCRIPTION:DESCRIPTORS:

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Oct-2009	BLA 125259		Cervarix Transmittal of Advertisements and Promotional Materials Advertising/Promotion	81531a8a

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Ms. The Central Document Control Room	Correspondence	TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL MATERIALS SUBTYPES: Advertising/Promotion SUBTYPES: Advertising/Promotion SUBINDEXING: Material: PEP - Professional Exhibit Panel - CVX293R0: Now Approved Material: WWW - Internet Promotion - CVX187R0: Cervarix.com - Now Approved Material: WWW - Internet Promotion - CVX277R0: GSKVaccinesDirect.com - Now Approved Banner

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
16-Oct-2009	BLA 125259		Cervarix Approval Letter N/A	8152ca8f

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Norman Baylor, Ph.D.	GlaxoSmithKline Mr. Matthew Whitman	Correspondence	APPROVAL LETTER SUBTYPES: N/A SUBTYPES: N/A Protocol: 104820 Protocol: 106636 Protocol: 109616/109624/109625 Protocol: 109628 Protocol: 580299/008 Protocol: 580299/009

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

Keyword: Submission Type - Original

DESCRIPTION:

FDA approved GSK's biologics license application for Human Papillomavirus Bivalent (Types 16 and 18) vaccine, Recombinant indicated for the prevention of cervical cancer, cervical intraepithelial neoplasia grade 2 or worse and adenocarcinoma in situ, and cervical intraepithelial neoplasia grade 1, caused by oncogenic human papillomavirus (HPV) types 16 and 18 in females 10 through 25 years of age.

DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
19-Oct-2009	BLA 125259; BLA 125259; BLA 125259		Cervarix General Correspondence CMC Labeling N/A	81539795

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mrs. Jennifer W. Haagen	Food and Drug Administration Ms. NA NA	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: CMC; Labeling; N/A SUBTYPES: CMC; Labeling; N/A
			GENERAL CORRESPONDENCE SUBTYPES: CMC; Labeling; N/A SUBTYPES: CMC; Labeling; N/A

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Oct-2009	BLA 125259		Cervarix Transmittal of Advertisements and Promotional Materials Advertising/Promotion	81536888

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL MATERIALS
Mr. Matthew Whitman	Administration		SUBTYPES: Advertising/Promotion
	N/A Evaluation and		SUBTYPES: Advertising/Promotion
	Research Center for		SUBINDEXING:
	Biologics, N/A		Material: PPO - Professional Print - Other - CVX301R0: New Product Announcement
			Letter

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
22-Oct-2009	BLA 125259		Cervarix	81536837
			Transmittal of Advertisements and Promotional Materials	
			Advertising/Promotion	

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL MATERIALS
Mr. Matthew Whitman	Administration		SUBTYPES: Advertising/Promotion
	N/A Evaluation and		SUBTYPES: Advertising/Promotion
	Research Center for		SUBINDEXING:
	Biologics, N/A		Material: PAD - Professional Print Ad - CVX185R0: Now Available

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Oct-2009	BLA 125259		Cervarix	8154c796



## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

015-Day ADR Report  
N/A

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	Correspondence	015-DAY ADR REPORT
			SUBTYPES: N/A
			SUBTYPES: N/A
			SUBINDEXING:
			ADRs: B0598292A
			ADRs: B0598302A
			ADRs: R0005824A
			ADRs: R0006691A

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
23-Oct-2009	BLA 125259	Sup#:	Cervarix Sup #: Supplement: Changes Being Effected Establishment Description	81530f41

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	Correspondence	SUPPLEMENT: CHANGES BEING EFFECTED
			SUBTYPES: Establishment Description
			SUBTYPES: Establishment Description

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DESCRIPTION:

GSK submitted an EST CBE supplemental application which provides information in support of the introduction of thiomersal free seasonal Flu vaccine (formulated on Ste Foy site) in the approved filling facility WN16 on the Wavre, Begium site

DESCRIPTORS:

ESG;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
26-Oct-2009	BLA 125259	Seq#: 0081	Cervarix Seq #: 0081 General Correspondence Other	815345b0

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Ms. Linda S. Kramer	Food and Drug Administration Mr. John A. Eltermann, Jr., R.Ph.	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
27-Oct-2009	BLA 125259	Seq#: 0082	Cervarix Seq #: 0082 Response to Approval Letter N/A	81538325

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Matthew Whitman	Food and Drug Administration Dr. Norman Baylor, Ph.D.	Correspondence	RESPONSE TO APPROVAL LETTER SUBTYPES: N/A SUBTYPES: N/A

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

27-Oct-2009 BLA 125259

Cervarix

8153fbe6

Transmittal of Advertisements and Promotional Materials  
Advertising/Promotion

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL MATERIALS
Mr. Matthew Whitman	Administration		SUBTYPES: Advertising/Promotion
	Ms. The Central Document		SUBTYPES: Advertising/Promotion
	Control Room		SUBINDEXING:
			Material: PPO - Professional Print - Other - CVX240R0: Ordering Card

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
29-Oct-2009	BLA 125259	Cervarix		8154386a
		General Teleconference		
		Other		

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Telephone Conversation	GENERAL TELECONFERENCE
	Administration		SUBTYPES: Other
			SUBTYPES: Other

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

No

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Oct-2009	BLA 125259	Cervarix		8153b548

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## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

General Correspondence

Other

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug Administration	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: Other SUBTYPES: Other

DESCRIPTION:

GSK Bio submitted the fifth Quarterly Progress Report which summarizes the Corrective and Preventive Actions (CAPA) and related activities that were completed at the GSK Bio Belgium facilities between July 1 and September 30, 2009 with respect to the commitments made in responses to the Form FDA 483 submitted on August 6, 2008.

DESCRIPTORS:

ESG;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
30-Oct-2009	BLA 125259		Cervarix Transmittal of Advertisements and Promotional Materials Advertising/Promotion	815442b5

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline Mr. Philip A. Witman, M.P.H.	Food and Drug Administration Ms. The Central Document Control Room	Correspondence	TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL MATERIALS SUBTYPES: Advertising/Promotion SUBTYPES: Advertising/Promotion SUBINDEXING: Material: PSL - Professional Slides - CVX270R0: Branded Slide Deck

DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
03-Nov-2009	BLA 125259		Cervarix	81544309

11/10/2009 10:33:50 AM

Page: 296 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

General Teleconference  
Other

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Telephone Conversation	GENERAL TELECONFERENCE
Ms. Linda S. Kramer	Administration		SUBTYPES: Other
	Ms. Rebecca Olin		SUBTYPES: Other

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Nov-2009	BLA 125259		Cervarix	81547f2a
			General Correspondence	
			N/A	

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug	GlaxoSmithKline	Correspondence	GENERAL CORRESPONDENCE
Administration	Mr. Paul Nelis		SUBTYPES: N/A
Dr. Jesse Goodman, M.D.			SUBTYPES: N/A
			SUBINDEXING:
			Lot Number: AHPVA096A
			Keyword: Biologics - Lot Release: Released

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Nov-2009	BLA 125259		Cervarix	8154952a

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11/10/2009 10:33:50 AM

Page: 297 of 299

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

General Correspondence  
N/A

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Jesse Goodman, M.D.	GlaxoSmithKline Mr. Paul Nelis	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: N/A SUBTYPES: N/A SUBINDEXING: Lot Number: AHPVA092A Keyword: Biologics - Lot Release: Released

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

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DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
05-Nov-2009	BLA 125259		Cervarix General Correspondence N/A	815494d9

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FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
Food and Drug Administration Dr. Jesse Goodman, M.D.	GlaxoSmithKline Mr. Paul Nelis	Correspondence	GENERAL CORRESPONDENCE SUBTYPES: N/A SUBTYPES: N/A SUBINDEXING: Lot Number: AHPVA088B Keyword: Biologics - Lot Release: Released

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DESCRIPTION:DESCRIPTORS:ELECTRONIC MEDIA: MEDIA INFORMATION:

No

QC COMPLETED: DATE REFERENCED:

Yes

## CARDS CHRONOLOGY REPORT

REPORT DATE RANGE All

DATE:	APPLICATION:	SER/SUPP/SEQ #:	RE LINE:	DOC ID:
06-Nov-2009	BLA 125259	Seq#: 0083	Cervarix Seq #: 0083 Supplement: Changes Being Effected Labeling	8154716b

FROM:	TO:	COMMUNICATION:	DOCTYPE & SUBTYPE:
GlaxoSmithKline	Food and Drug	Correspondence	SUPPLEMENT: CHANGES BEING EFFECTED
Mr. Byron Bravo	Administration		SUBTYPES: Labeling
	Dr. Norman Baylor, Ph.D.		SUBTYPES: Labeling

DESCRIPTION:DESCRIPTORS:

ESG;ECTD;SAFE

ELECTRONIC MEDIA: MEDIA INFORMATION:

Yes

QC COMPLETED: DATE REFERENCED:

Yes